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July 1993 Vol. 63, No. 1

Alabama Medicine

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

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Credentialing Issues

By John T. (Jack) Mooresmith, Esq.

Healthcare reform has thrust credentialing into the forefront of issues facing Alabama physicians

--pg.6

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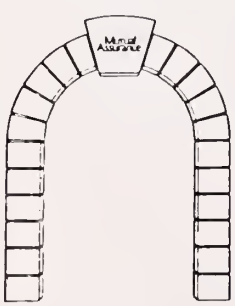
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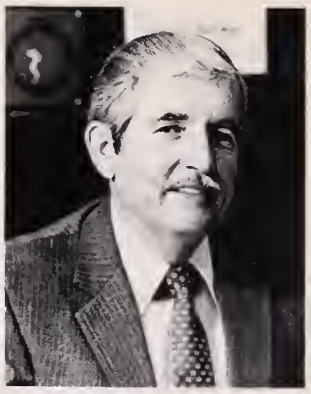
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Alabama Medicine at age 62

After literally decades of discussion, in July 1931 the Medical Association of the State of Alabama published the first issue of this magazine (with the original title retained today in the subtitle). Thus this issue, Vol. 63, No.1, incorporating the unpublished last four issues of the previous volume year, begins the 63rd year. That epochal period was chronicled in these pages as the best of times and the worst of times for medicine. The old Latin motto of MASA, loosely translated "We hope for better days," seems singularly appropriate in 1993.

EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

The Culture of Medicine

In my last column, I touched on the primal fear of those in medicine, and those of us close to medicine, that the policy wonks who went to Washington with the firm conviction that they could, as they said, "re-invent government" held the same incredibly naive views about medicine — that by a few non-stop discussions among a few hundred hand-picked wonks they would re-invent medicine from the ground up in far less than the 100 days originally promised.

Mr. Clinton himself had blocked out exactly 15 hours to devote to thinking about the various recommendations of his wife's secret and anonymous task force and to making his decisions about each —15 hours to re-invent a system, the product of centuries of evolution, that is one of the brightest jewels in the crown of Western civilization.

In their overweening arrogance, the Clintons have shown a fascination for endless conferences. The meetings of Hillary's Tower of Babel would often drag on for 13 or 15 hours of exhausting talk among certified theoriticians. Unencumbered by any representative of those with practical experience, such as the American Medical Association, the conferees solved all the problems in one of the most complex undertakings in the history of government.

And they achieved all that in the same way they solved the other problems of the world back during their undergraduate days — by non-stop rap sessions. The President himself got in the act later, calling his staff together at the end of business one Friday night, when all were heading for home, for an exhausting four-hour talk-fest which he declared to be "fun" although no answers were forthcoming.

When it finally came time to actually write the often-delayed bill, a few dozen of the original task force were summoned. Each was given a section of the proposed law, which he or she was not to copy, record or mention to anyone. Each was isolated from the others; none was shown any of the sections of the bill other than their own brief section.

How is it possible, more than one of these Kafkaesque prisoners wondered, to write something this complex without knowing what it is connected to, how it fits into the whole? Absurd, of course, but no more so than locking out the AMA and other riffraff in the original meetings.

These children of the 60s are, it appears to me, still children. They are still spaced-out on the heady wine of their own egocentricism and hypnotized by the sound of their own pretensive patter. They believe that they and their pals from the hallowed halls of Oxford, Yale and Harvard can brainstorm any problem after reading a monograph or two by some other wonk.

I was reminded by *U.S. News & World Report* that the real antecedent to this kind of problem-solving in a vacuum was Secretary of Defense Robert McNamara. He was the number-crunching theoritician of his day who attempted to reinvent the military services in a more cost-effective manner. In doing so, he refused to listen to the generals and thus invented new programs and weapons systems that made perfect sense to his whiz kids but systematically violated the military culture.

None of the systems survived for long after his

tenure. The *U.S. News* writer made the point that the military culture produces men (and now women, of course) who will risk career and life itself for what they believe is right for the country. McNamara blithely ignored this culture, attempting to impose on it a canned, cost-analysis logic that was surely brilliant in its own way but utterly detached from the reality of what makes fighting forces work, as well as the nature of the threats in the real world.

The *U.S. News* writer noted that the Marine Corps is on everybody's list of one of the most effective fighting forces of all time. And yet no McNamara or Clinton could invent such a force, which is what it is not because of its weapons but, first of all, because of its culture, the esprit that produces men willing to die for the Corps. Have you ever heard an old Marine, no matter how many years removed from his service, badmouth the Corps? Once a Marine always a Marine.

What the Clinton's have ignored, the writer suggests, is the far more powerful "culture of medicine." It is even more mysterious and, it should be quickly added, fragile. Neither Hillary nor Bill, for all their intellectual achievements (real and imagined), could invent a new culture of medicine founded on the computerized cost-accounting approach to human health and life. For that matter, there is no way they can adequately comprehend the existing culture of medicine any more than McNamara could comprehend what made the military culture work — and win wars.

It occurs to me that one writer has finally touched on what the great debate of 1993 is all about. It's not about doctors, hospitals, technology, disease or even money. It's about the *culture of medicine* and how far government can dare go in tampering with that culture without risking irreversible and cataclysmic damage.

But it did appear that Mrs. Clinton, in her June speech to the AMA, was beginning to comprehend. I hope Mr. Clinton listens to her.

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PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

You Can Make A Difference

Following is the text of Dr. West's comments to the College of Counsellors and House of Delegates at the annual business meeting in April.

Mr. Speaker, Members of the House, Officers, and Guests—

I thank you very much for allowing me the privilege of serving you and MASA as President this next year and as alternate delegate to the AMA.

I want you all to understand just how much power comes with the office of President. For example, the Speaker just said, "keep it brief," and I responded, "yes, sir." I will try to keep my remarks brief.

I also just asked Dr. Morris if he had any last-minute advice, and he said: "Just skip this year and go right on to the office of Past President. You can't believe the wave of relief that will come over you."

First let me introduce to you the Vice-President for this term, Dr. C. Neal Canup. He's better known as Buddy, and I will ask him to stand. His job this year is not just to serve in the event I become unable to carry out my duties. He will also serve as an advisor to me, be a sounding board for any proposals I might have, and serve as a vital member of the Association Affairs Committee. He has been a great friend to me and will not hesitate to call my hand or give advice if he thinks I am not on the right track.

This may be a very memorable year in the history of the Association. So far, none of us has any facts about what the Clinton Administration has planned for the health care industry. We have all heard several tentative proposals or considerations, and I am very concerned about what might happen to our profession and to us as physicians. I am more concerned, though, about what may happen to our patients in a reformed health care system. Our principal concern is not about provider payment as it relates to our income but rather about how it impacts on patient access to care.

Does the health care system need a reformation? Reform means to form again, to reconstruct, to make different in shape and form. The implication is that a change will make the system better. If so, how can we argue against that? Do we need change?

If it means copying the system that exists in other countries such as Canada, Germany, or England, then I say no.

If it means decreasing the intrusion of the federal government into the day-to-day practice of medicine, then I say yes.

If it means improving access to care for all patients and for a reasonable cost, then I say yes.

If if means limiting the patient's choice of provider, then I say no.

My grave worry is that the spring of '94 will bring many more no's to our lips than yes's.

The concepts of free enterprise have made this country great. There are important lessons to be learned from history. Just look at what's happening to those socialistic and communistic countries.

Perhaps we only need reform of the Medicare and Medicaid system. Or maybe we should first begin with those programs before we try to make adjustments to the great system we already have in the private sector.

I believe it is impossible to provide more services to more patients for less money. That mentality does

not work in my household, it will not work in my practice, and it will not work for the federal government — no matter how many times this Administration says that it will.

Facts: The health care system in these United States is not the sole cause for the escalation of the budget deficit or the national debt of over $3 trillion as our President would have us and the public believe.

There are four ways to decrease the cost of health care:

1. Decrease what you pay providers for their service to patients
2. Limit the care that patients may receive from providers
3. Decrease or limit the number of recipients who can get care
4. Limit research and training programs

It will probably take all four to realize any significant cost savings. Number 3 will not even be considered. The plan is to cover 37 million more. 1 and 2 would probably work; but without 3 there will need to be a tax increase to pay for the system.

How has money spent in the private sector contributed to the national debt?

Who says 12% to 15% of our GNP is too much to spend on health care?

How much of the total spent on health care is attributed to entitlements such as Medicare and Medicaid?

Perhaps reform should be with the government programs.

Perhaps reform should be congressional reform. How nice it is to arrange an automatic raise each year with out having to vote publically for it and at a time when every one else is being asked to "bite the bullet" and "sacrifice."

Congress just did that.

How can they claim that government health care spending is growing so much faster than inflation when what the government pays doctors is a discounted fee schedule and has planned decreases through 1996?

How reliable is that claim when hospitals are paid by DRGs and when that reimbursement is most often less than the cost to provide the service?

The answer must be: there are more people who are getting federal care every year than are dying off the entitlement rolls. It could also be possible that the quoted figures are wrong. It is difficult to know what to believe when one gets so many different accounts of the federal budget deficit from different sources within the government.

MASA has a plan for health care reform in Alabama. It embraces many of the same concepts as proposed by the AMA; and, hopefully, we will soon go public with the details.

What can you expect from your leaders this next year?

You can expect us to take the initiative in formulating a plan for Alabama. We will try to do damage control with whatever comes from Washington. And, if given the opportunity, we will try to influence on the front end whatever reforms develop.

We will try to meet head-on and deal with whatever is presented to organized medicine, whether it be a hurdle or an opportunity.

We will try to keep you informed and in a timely manner about what is going on with the Association and with the changes from Washington and from the Alabama legislature.

MASA board members and staff and I cannot do what needs to be done alone. You must help. You must be involved. Your very presence here today indicates you have an interest in the workings of organized medicine....and hence, in your profession.

We must be partners, and we must form partnerships. Alone we can do very little; but together and united we can stand against whatever confronts us. And by standing united together and with our friends, we can prevail.

I have often asked myself why I have spent 11 years of my life attending to MASA business, why I would accept the call to be President, and why I or anyone would want the job.

The answer has to be: because I feel I can make a difference. And I believe that's what drives most of us to give so much for the cause. And because the work of the Association is so important!

You, too, can make a difference!

Again, I thank you for the privilege of serving as an officer of this great association. And I thank you for listening to what I have to say.

I want you and I to be the catalyst for change when it is needed and for strength when it is called for!

Credentialing Issues Created By Health Care Reform

*John T. Mooresmith, Esq.**

Presented at an Alabama State Bar Association seminar for doctors, hospital administrators, and their attorneys on May 22, 1993. MASA's Board of Censors has commissioned the development of a set of model bylaws for hospital medical staffs. Mr. Mooresmith's article points up the central importance of that project.

If there is any unanimous consensus, it is that the health care system as we know it is going to be changed. Although the scope and extent of those changes are unknown, there is enough comment and criticism already on record for us to reasonably predict some of the inevitable changes that will occur.

Since those primarily expressing concern over the present system are those paying the bills, changes in the system of reimbursement will almost certainly be made. One possible method of change that has been discussed takes the form of channeling payments for physician and ancillary services through hospitals by bundling them into a global Diagnosis Related Group ("DRG") reimbursement scheme. This would place hospitals at risk for excess charges or services, and would force hospitals to reduce that risk through internal means. This reduction could come through selective contracting with providers or through intensified scrutiny of medical staffs as a whole, or both.

Even if the channeling approach is not implemented, some form of limitation on the total amount of dollars available for treatment of patients will occur. Presently DRGs are only applied to Medicare patients. It may be that private employers and insurers will also adopt this approach. If so, then the financial risk to hospitals will increase. Even without DRGs in the private sector, some type of restriction on the flow of health care dollars is inevitable. The term used to describe restrictions on the operation of the health care industry is managed care. It is presently in place in programs such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs). Most patients, however, are not covered under these types of plans. In the future, though, managed care will be the norm rather than the exception. Management of care to the uninitiated is taken to mean limitation on unnecessary care or reduction of excessive charges. However, in the real world, much of the "fat" so to speak has already been trimmed from the health care system. What this means is that in the future payers will be paying less for essential treatment.

In assessing the health care system to locate the focal point of much of the total cost, attention has been focused on hospitals. This is due to the fact that much of the expensive treatment in the health care system occurs in the hospital. For those who wish to contain their cost for treatment, the hospital seems a logical place to focus their efforts. The hospital is seen as the core of the system. It is the location of the most expensive segment of costs, and it has the administrative apparatus to establish and implement monitoring systems over charges, services, lengths of stay, equipment and practically every facet of health care. It has the ability to control most areas of cost, except for individual physicians, and the treatment they order.

In an effort to gain control over the total spectrum of health care, hospitals have integrated many of the ancillary service organizations into their present corporate structure. Hospitals now own or control nursing homes. Hospitals own or control home health agencies. Hospitals own or control durable medical

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equipment companies. Hospitals own or control free-standing imaging centers. Hospitals own or control ambulatory surgery centers, laboratories, physician office buildings, walk-in clinics, and even physician medical practices themselves.

In order to gain control over the last remaining autonomous health care providers, many hospitals have formed nonprofit professional corporations to acquire medical practices. This has been accomplished by having the nonprofit professional corporation purchase the stock of existing physician professional corporations. Control is then gained over the physicians through their employment contracts with the acquired professional corporations. To the rest of the world it appears nothing has changed. The physicians continue to practice under the corporate name they have historically used. However, the hospital, through ownership of the professional corporation, is now the boss.

By the hospital using a nonprofit, though taxable, structure, there are no stockholders who can elect or remove the board of directors. Since Alabama law only requires that one director and the president of the professional corporation be a physician, the employed medical director of the hospital usually fills this role.[1] Management of the professional corporation is conducted by the board of directors, which is usually comprised of the administration of the hospital.

Acquisition of physician medical practices in this manner, however, is both expensive and risky. Medicare and Medicaid AntiFraud and Abuse Provisions prohibit the payment of any remuneration, overtly or covertly, directly or indirectly, where a material purpose of the payment is to induce the referral of Medicare or Medicaid patients.[2] Presently under consideration by the Congress is a bill which would extend this prohibition to all patients regardless of the source of payment.[3] This would close the loophole which hospitals presently use to acquire existing medical practices. Once the acquisition is accomplished, the physicians refer their Medicare and Medicaid patients to another facility. Since the anti-fraud and abuse provisions only apply to Medicare and Medicaid patients, the law is not violated. Once the anti-fraud and abuse provisions are applied to private patients, such as Blue Cross - Blue Shield, the attractiveness of physician practice acquisitions will diminish if not evaporate.

Faced with possible felony prosecution for violation of these provisions, as well as the expense of acquisition (which may be an amount equal to the previous year's gross revenue of the practice), several hospitals have considered the direct employment of physicians as an alternative. Alabama does not have any prohibition on the corporate practice of medicine either by statute, case law or regulation.[4] Sears Roebuck could employ a physician, pay the physician a salary, charge customary rates, and retain the profits. The physician's services could even be charged on the Sears Revolving Charge Account. The only restriction is the position of the Alabama Board of Medical Examiners that the physician must retain control over his medical decisions. While the employment agreement would certainly contain a disclaimer regarding the exercise of medical judgment by the physician (as do most managed care agreements), the direct employment of physicians gives hospitals tremendous leverage over the manner in which the physicians practice. Obviously, referrals would go to the employer/hospital in any cases where the hospital had the means for treatment, but the hospital would also gain a large degree of influence over the medical decisions of the physician as well. If the hospital were to discuss with the physician that, for example, he was putting too many indigent patients in the facility, or that his lengths of stay were excessive, or that he was ordering too many scans, the import of the discussion would not be lost on the physician/employee. Such direct employment of physicians by hospitals would not only be legal under Alabama law, but would also fall within a specific safe harbor for fraud and abuse (in fact, bona fide employment relationships are an exception to the federal and state fraud and abuse statutes).[5]

Needless to say, physicians in private practice have not been enthusiastic about hospitals hiring physicians or acquiring medical practices. An attempt by practicing physicians on a hospital medical staff to prohibit the direct employment of two primary care physicians by the hospital was met with antitrust litigation.[6] While the physician defendants were ultimately successful in court, the expense, emotional strain, and disruption of their personal lives and practices was substantial. Fear of antitrust prosecution will keep most physicians from attempting to prevent this type of employment. That fear is both realistic and justified. At a recent meeting of the National Health Lawyers Association, Clinton Administration Transition Team representatives served notice that they will not hesitate to apply and enforce the antitrust laws against the medical profession.

The acquisition of physician practices and direct employment of physicians are presently being implemented in Alabama as means by which hospitals are

seeking to position themselves for the changes that are coming in the health care industry. These strategies are overly expensive and burdensome, however, for hospitals to attempt on a very broad scale. Aside from the acquisition expense of medical practices, the continuing operational expense of either subsidiary medical practices or employed physicians is not attractive to many hospitals. These hospitals are looking for ways to reduce their fixed overhead to meet the challenges ahead, not increase that overhead.

Previously, hospital control of physician referral decisions (fraud and abuse aside) was seen as a competitive tool for survival by hospitals where the physician was the key to developing and maintaining a healthy patient census. Hospitals received patients only when those patients were admitted by a physician. Hospitals provided diagnostic and therapeutic services for patients only when those services were ordered by a physician. Hospitals courted physicians for their referrals, and when that failed sought one way or another to buy the physician's loyalty. Hospitals used terms such as physician/hospital bonding or physician recruitment to describe their competitive attempts to secure a continuing patient and revenue stream.

This is the system that the Clinton Administration plans to change. The fundamental basis of the system was that the more admissions a physician made, the more services the physician ordered, and the longer the patient stayed, the more profitable the hospital became. Previous efforts, notably the DRG system of reimbursement, have reduced the incentive for long hospital stays. Private payers, through managed care programs, established preadmission certification and utilization review requirements that also reduced the ability of physicians to admit patients and keep them in the hospital. Preadmission certification requires approval by the payer prior to admission for elective surgeries. Utilization review is used by payers to determine how long the patient should be hospitalized. If the hospitalization goes beyond that point, the payer is released from the obligation for payment.

Utilization review can be either concurrent or retrospective. Concurrent review is used to determine how long the patient should be hospitalized, and is performed at the time of admission. A certain number of days for that hospitalization are designated, and the payer will not pay for more than that number of days unless extenuating circumstances occur. Retrospective review is performed after the fact, and is used to recoup payments which the payer determines were made for services which were not medically necessary.

In one case, a hospital with a psychiatric unit which had patients admitted for months at a time was audited by a payer on a retrospective review. The psychiatrists reviewing charts for the payer determined that the hospitalizations were excessive in length, and that the patients could have been treated on an outpatient basis after a brief hospitalization. The payer demanded that the hospital repay the cost of the audited hospitalization (which was several hundred thousand dollars), and then proceeded to audit all of the admitting psychiatrist's prior hospitalized patients who had coverage by that payer. The hospital was in a serious dilemma. It could not refuse the patients the psychiatrist admitted, but risked massive loss if the hospitalizations were later denied on a retrospective basis. This hospital ultimately closed its psychiatric unit.

Although utilization review has shortened hospital lengths of stay, existing methods of cost containment have not been effective in reducing significantly the cost of services ordered by physicians. This is fertile ground for the reformers of the health care system. Changes are going to come which will create an incentive for hospitals to provide less rather than more care. This incentive may be given to hospitals in various ways from bundling physician fees, hospital and ancillary services into one global payment, to penalizing hospitals through retrospective denial of reimbursement for admissions or services ordered by physicians.

One way or another, the incentive to provide less service will be imposed on hospitals. How will hospitals respond to this new responsibility? Particularly, how will hospitals respond to the economic risk they will assume from the medical decisions made by the members of their medical staffs?

We cannot assume that hospitals will ignore the potential threat to their financial viability that will be presented by certain members of their medical staffs who order more tests than most other physicians, or keep their patients longer for the same diagnoses than most other physicians. Computer profiles will identify these physicians, and they will not be ignored. Arguably, the members of the hospital board of directors or trustees would fail in their fiduciary responsibility to the institution if such information was ignored.

How will hospitals respond? This will be the newest, and perhaps the greatest, area of conflict between hospitals and their medical staffs. Hospitals will have the incentive, if not the responsibility, to

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Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries. **Acute Abdominal Conditions**: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions. **PRECAUTIONS: Special Risk Patients**: VICODIN/VICODIN ES Tablets should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. **Cough Reflex:** Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when VICODIN/VICODIN ES Tablets are used postoperatively and in patients with pulmonary disease. **Drug Interactions:** Patients receiving other narcotic analgesics, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with VICODIN/VICODIN ES Tablets may exhibit an additive CNS depression. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus. **Usage in Pregnancy: Teratogenic Effects:** Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN/VICODIN ES Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic effects:** Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. **Labor and Delivery**: Administration of VICODIN/VICODIN ES Tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from VICODIN/VICODIN ES Tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use**: Safety and effectiveness in children have not been established. **ADVERSE REACTIONS**: The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: **Central Nervous System:** Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes. **Gastrointestinal System**: The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN/VICODIN ES Tablets may produce constipation. **Genitourinary System**: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported. **Respiratory Depression:** Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated. **DRUG ABUSE AND DEPENDENCE:** VICODIN/VICODIN ES Tablets are subject to the Federal Controlled Substance Act (Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, VICODIN/VICODIN ES Tablets should be prescribed and administered with caution. **OVERDOSAGE: Acetaminophen Signs and Symptoms:** In acute acetaminophen overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. **Hydrocodone Signs and Symptoms**: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, (cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

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monitor, assess, modify and possibly restrict the medical treatment decisions of the members of the medical staff when those decisions result in unnecessary financial risk to the institution.

Medical staffs, on the other hand, are comprised of physicians who owe a fiduciary responsibility to their patients to provide those patients with the appropriate standard of care.[7] Failure by a physician to provide that standard of care leaves the physician vulnerable to medical malpractice litigation by the patient. This leaves the physician in a catch-22 situation. If he refuses to discharge a patient within the time limits established by concurrent review, he risks the anger of the hospital and the patient, if payment is denied. On the other hand, if he discharges the patient prematurely, and the patient suffers an injury, he will be sued for failure to provide the appropriate standard of care to the patient. Not only are hospitals reluctant to agree to indemnify physicians who cooperate with cost containment procedures, most if not all managed care agreements specifically disclaim any infringement on the medical decisions of physicians. The physician is left with total responsibility to the patient, and conflicting pressure from the payer and the hospital. By using innocuous terms such as medically necessary, payers are actually rationing care they have agreed to cover. They are rationing care, but refuse to publicly acknowledge that fact.

Rationing of health care will be inherent in any of the managed care systems of the future. Few, if any, people have heard anyone from the Clinton Administration, Business, or the Insurance Industry proclaim the merits of rationing the health care that most Americans take for granted. In fact, those who espouse managed care go to great lengths to assure patients that they will receive quality medical care, but in a more affordable manner.

Such statements are merely a smoke and mirrors argument. For the cost of health care to be substantially reduced, the demand for health care must be controlled. Since the demand for specific treatment services is generated by physicians, pressure will be placed upon physicians to order less. That premise raises an interesting question of informed consent. The doctrine of informed consent has been applied in circumstances where a physician is alleged to have failed to provide a patient with sufficient information for that patient to make a knowledgeable decision as to alternative courses of treatment.[8]

In a managed care plan, the physician is pressured to make decisions or choices for the patient based on economic considerations. What of the obligation of the physician to communicate information to the patient? If a certain test may in a small percentage of circumstances produce data upon which a diagnosis can be made, but that test is expensive, and usually redundant, should the patient be given the opportunity to pay personally for the test? If not given the choice, is the physician subject to suit for the reverse of traditional informed consent, i.e., the ability for the patient to have done something the physician had not planned to do?

This ethical and legal dilemma of rationing the health care of patients is at the heart of what is known as economic credentialing. Economic credentialing is the sword that hospitals will use to force the physicians on the medical staff to consider the financial impact their decisions have on the institution. It is the tool that will be used to remove from the medical staff those physicians the hospital feels are not economical in their treatment decisions. The AMA has defined economic credentialing as the "use of economic criteria unrelated to quality of care or professional competency in determining qualifications for initial or continuing medical staff membership or privileges."[9] The linchpin of this definition is the phrase "economic criteria unrelated to quality or competence." Historically, the purpose and reason for being of a medical staff was to assure that the physicians practicing at the hospital provided proper quality of care to patients in the hospital. In fact, the professional criteria for granting clinical privileges in the credentialing process, according to the Joint Commission on Accreditation of Health Care Organizations (JCAHO), are to be designed "to assure . . . that patients will receive quality care."[10]

Economic pressures on hospitals, however, will force them to consider some form of economic credentialing as a financial necessity. The AMA report which defined economic credentialing cited a 1991 survey of more than 500 hospital CEOs, conducted by the American Hospital Association publication, *Hospitals* magazine in which 41.7% of the respondents reported their belief that, within the next five years (now three), hospitals will consider physician's economic contributions when renewing privileges. In that same survey, 71.4% of the CEOs indicated that it is currently their practice to prepare economic profiles of medical staff members for "educational purposes." Conflict between medical staffs and hospitals is inevitable when you couple the basic mechanisms for economic credentialing that are rapidly being implemented by hospitals with the inclination to utilize the information being developed in economic

profiles of physicians.

What are the mechanisms for economic credentialing? These mechanisms are provisions which are inserted into the medical staff bylaws. Medical staff bylaws are lengthy documents (50-150 pages) which define the relationship between the hospital, the medical staff and individual physicians. Generally, bylaws are rules for the governance of a single organization which are adopted by the members of that organization. Medical staff bylaws, however, are a hybrid type of bylaws. Medical staff bylaws are produced and adopted by both the medical staff, generally an unincorporated association, and the hospital, a corporate entity. The medical staff bylaws set forth the procedures that are followed in determining which physicians can practice in the hospital, and what procedures they can perform. The medical staff bylaws also specify the rights and responsibilities of the physicians who are on staff.

Medical staff bylaws are jointly adopted by the medical staff and the hospital, and are the method by which the hospital fulfills its responsibility of assuring that the quality of care practiced by physicians in the hospital meets appropriate standards. In recent years, the acceleration of medical malpractice and negligence awards against both physicians and hospitals has caused hospitals to turn more to the credentialing process. In the ensuing disputes over medical staff privileges, courts have looked to the medical staff bylaws for guidance as to the respective rights, obligations and responsibilities of individual physicians and the hospitals where they practice. Courts in some states, such as Tennessee, have considered medical staff bylaws to be a binding contract, imposing enforceable legal obligations on both the medical staff and the hospital.[11] Whether considered a contract or not, however, medical staff membership and privilege decisions based upon clear directives in the medical staff bylaws will probably be upheld.

Given the serious nature of medical staff bylaws, care should be taken in their drafting and amendment. Language should be clear and any ambiguities should be clarified in the bylaws. Oral explanations at committee or medical staff meetings and references in the minutes may not be sufficient. It is critical that the dual approval status of medical staff bylaws be maintained if the inevitable conflict between hospitals and medical staffs is to be minimized. Hospitals are being advised, particularly in light of the trend to consider medical staff bylaws as contracts, to insert discretionary language in the bylaws that allows unilateral action by the hospital. An example of this type of provision is:

The affirmative vote of a majority of the Board of Trustees is necessary, provided that the Trustees may resort to its own initiative in formulating or amending Medical Staff Bylaws. In such events, Staff recommendations and views shall be carefully considered by the Trustees in its deliberations and in its actions.

In the above situation, amendments do not have to be initiated by the medical staff, no staff vote is required, and the Board may act independent of the staff with regard to amendments.

The danger in unilateral amendment is that factors such as economic credentialing can then be imposed without medical staff approval. This, coupled with the authority all bylaws give the governing board to initiate disciplinary action against physicians, and to disregard medical staff recommendations on privileges, gives the hospital total control over the medical staff.

A more subtle method of gaining control by hospitals is the movement to make medical staff bylaws merely a skeletal document with the major provisions contained in separate "policies." These may be "hospital policies," "credentialing policies," "fair hearing policies," "clinical privilege policies," etc. This weakens the concept of medical staff bylaws as being considered a contract and has been criticized by the AMA. Portions of medical staff bylaws that are removed and placed in policies may not be subject to medical staff agreement. Hospitals may be able to amend these policies independent of the medical staff and avoid the requirement of the Joint Commission on Accreditation of Health Care Organizations that neither body may unilaterally amend the medical staff bylaws.[12]

Examples of medical staff bylaw provisions that authorize economic credentialing are:

[When medical staff membership or clinical privilege determinations are being made] consideration will be given to utilization patterns, present and projected patient mix . . . and the hospital's specific goals and objectives as reflected in the hospital's short and long-range plans.

* * * * *

An investigation shall be initiated whenever there is reason to believe that the activities or professional conduct of any staff member or other practitioner having clinical privileges may be . . . disruptive to the efficient operation of the hospital or any of its departments or services; inconsistent with rendering quality patient care in a cost-effective manner.

Failure of a practitioner to notify the hospital immediately if he receives notice of denial of payment or notice of proposed or actual sanctions against him in connection with Medicare or Medicaid program participation or any private treatment review shall be deemed to be inconsistent with rendering quality patient care in a cost-effective manner. . . . The hospital retains the absolute right to increase its standards for practitioners and to take appropriate action against practitioners who do not meet the higher standards.

* * * * *

The Credentials Committee's review shall include the member's admission patterns and patterns of care.

* * * * *

[Reappointment] may be denied on the basis of inconsistency with the hospital's written plan of development including the mix of patient care services to be provided. . . .[13]

The inclusion of economic criteria in the arena of credentialing is seen by many hospitals as a necessity for their financial survival in a new age of managed care. For the physicians, it creates a substantial risk that they will be motivated, if not required, to change their medical practices to the detriment of patient care in order to satisfy the non-quality criteria. Many physicians feel that their colleagues who render excellent patient care should not be penalized for reasons not related to patient care. They feel that economic credentialing is a movement oriented toward holding physicians accountable, not only for their clinical performance, but for their fiscal performance and how their practices affect the financial positions in which they hold privileges. These physicians will be accountable to the hospital on the one hand for their financial impact, and will be accountable to their patients on the other hand for the quality of their services.

How should these conflicting goals be addressed? The economic realities of the new era that is on the horizon cannot be ignored. The availability and cost of health care in America has become a number one priority for the new Administration, and for industry. While availability is always presented first in discussing the health care priorities for the nation, in reality it is the cost of health care which is first in the minds of the reformers. The present system will be changed. Some of the more radical measures that will take Congressional approval may take longer, but there are many changes which the Clinton Administration can implement by regulations through the Medicare and Medicaid Programs. Hospitals and physicians must address the problems of cost in the system if they wish to be ahead of the curve that is coming.

Economic credentialing will be one of the first changes in the new system regardless of the form the system takes. For hospitals to be able to compete with each other on the basis of cost, they feel they must be able to protect themselves from physicians who do not practice cost efficient medicine. Physicians must recognize this trend and work within the system to prevent pressures being placed on physicians to practice poor quality medicine under the guise of cost efficiency.

How can physicians moderate the effects of economic credentialing? The first step is education. Physicians must become knowledgeable about the changes that are coming, and the pressures that their hospitals will face. By becoming aware of the forces pressing their hospitals, physicians can become active participants with their hospitals in formulating appropriate changes and responses. If physicians ignore the competitive pressures on hospitals they lose the opportunity to have input into and affect the hospital's response.

Second, physicians must be sensitive to any changes in their medical staff bylaws which would allow a hospital to act unilaterally to implement credentialing criteria or unilaterally to amend the medical staff bylaws. Physicians must protect their right to be participants in deciding the issues that deal with credentialing. With this right, however, comes the responsibility to work reasonably with the hospital to accomplish the goal of controlling the cost of health care without sacrificing quality.

Third, the medical staff, through its leadership and appropriate committees, should be involved in the development of any models for economic analysis of physician performance in the hospital. These models should not be developed exclusively by hospital retained consultants and imposed upon the medical staff by administrative fiat. The models should be carefully reviewed by the medical staff to assure that issues such as severity of illness are considered in the development of economic measurement tools. The physicians still owe a fiduciary duty to their patients to act in those patients' best interest. Quality of care cannot be lost due to economic pressures, however severe those pressures may be. The medical staff must require or obtain validation that the economic performance indicators to be used are consistent with quality concerns. While the initial burden may be upon the

hospital to establish such validation, the medical staff may consider having an independent review.

Finally, the medical staff must retain control over the fair hearing procedure for membership on the medical staff and clinical privileges. This is the ultimate battleground over access to hospital facilities. If the economic measurement tools and the economic criteria are reasonable, the final piece of the puzzle is for the medical staff to act in a reasonable manner to educate its members as to the economic realities of the new era, and to weed out those physicians for whom education fails and whose practice patterns continue to be excessively expensive with no realistic tie to quality.

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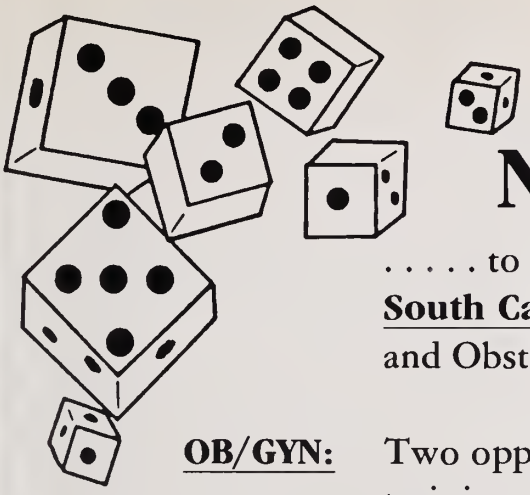
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In 1841, four doctors incorporated the Medical Society of Mobile County. The first medical college in Alabama, the 34th in the United States, was begun in Mobile when 111 students matriculated for the first classes in 1859.

At its meeting in November 1992, the Medical Society of Mobile County commemorated these events with a program depicting common medical problems of the 1850's, especially yellow fever; the cultural milieu of the era; and the contributions of prominent figures to the enfolding panorama of medical history in our area.

This photograph shows the plaque erected on the site of the Medical School. Left to right are: Dr. Ralph Pfeiffer, program chairman for the annual meeting; Mr. Michael Dow, mayor of Mobile; Mr. Paul J. Sousa, acting superintendent Mobile County Public Schools; and Dr. Robert McGinley, president of the Medical Society of Mobile County.



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Stress and the Physician's Family

Nicholas E. Stratas, M.D.

π Physicians are confronted daily with stresses that are unique in society. The stress of the medical family in social relationships is compounded by the demands of our profession. We are taught to be infallible, to never make mistakes, to never get sued, to be all powerful, and to stop any disease or tumor. Some of us become compulsive, workaholic, stoic physicians. This may be good for patients but is bad for the doctor and very hard on his spouse. Some turn to substance abuse in an attempt to relax the day's stressful events. Unfortunately, unhealthy adaptations are often unproductive, resulting in a poor quality of life for the doctor and his family.

In very clear words, Nicholas E. Stratas, M.D., offers specific explanations for the source of stress and offers practical recommendations for health coping mechanisms. Dr. Stratas is a psychiatrist who practices in Raleigh, North Carolina. He has treated many professionals and their families over the years and conducts one of the longest running couples groups in North Carolina. He is a past member of the North Carolina Impaired Physicians Program Board of Directors and is current President of the North Carolina Board of Medical Examiners. His comments, which follow, are quite timely.

Gerald L. Summer, M.D.
Medical Director
Physicians Recovery Network
Stress and the Physician's Family
Nicholas E. Stratas, MD

Stress is the wear and tear of living; the speed with which each of us lives and uses up one's self. The stress syndrome is the fight-flight reaction mediated by the sympathetic part of the autonomic nervous system. The impact which we can have on our own autonomic nervous system is significant.

Stress arises from three sources: first, the personality, "how I am," one's makeup, including genetic, developmental and family constellations. Secondly, self-management,"how I use myself," personally or professionally. Third, environment, or simply, "how I let the world wear me down," my relationships and the medical profession's requirements.

Rather than stemming directly from medical training and practice, evidence is that the difficulties arise primarily out of the psychological profiles of men and women who go into medicine.

The interactions between the stressors and the physician can be complex and unique. One physician's relationship with his wife deteriorated because he had become exhausted working extended hours due to the loss of a colleague. Another physician had a poor marital relationship and attempted to escape it by working an equally large number of hours per week. Not surprising, "caretaking" is often the underlying dynamic in the physician's marriage. This can lead to a later adult-to-adult relationship where caretaking is secondary or may lead to hostile relationships when dependency needs are not met and the partners strike out or move away from each other.

The following are various sources of stress:

(l) The need to take care of other people — This is more than adequately met for the physician in providing for patients. This can create a sense of crowding and lack of privacy for the physician. The reaction may be to expect more care from the spouse and, if the care is not forthcoming, to demean the spouse. It may lead to excessive distancing. Closeness is crucial.

(2) The need to be in control — In the practice of medicine there is a constant demand for management of change while at the same time an on-going demand for containment of feelings. There is an exaggerated use of denial, repression and suppression, not always maladaptively. This reinforces detachment from personal feelings and from feelings of members of the family. There are also attempts to control one's own feelings and those of the family.

(3) The need to function in a competent manner with constant high self-expectations — This is considerable and is reinforced by the profession itself and by the medical malpractice climate. It is frequently accompanied by a lapse into incompetence within the family structure.

(4) Constant decision-making demanded of physicians — This may encourage taking over decisions that need to be made by others, pre-empting spouse's or children's own responsibility. Inefficient decision

— making may show up in the form of absence in the partnership or in the parenting process.

(5) Constant exposure to illness, handicap and/or loss — This reinforces the use of denial or detachment and carries over into the family. Symptoms in the family may be ignored or be approached with overreaction and over treatment.

(6) A physician's family priorities often take a back seat to the expectations of fellow colleagues, referral agencies, hospital staffs, office staff and insurance companies — The double-bind is that the physician wants personal and professional approval and often does justice to neither.

(7) Time pressures and long hours — Internship and residency provide the first exposure to long hours. While workaholics are lauded in our society as some type of contemporary hero and frequently are the brightest, most successful people, the price they pay is high. During five years, 55.5% of internal medicine training programs granted leaves of absence to medical residents because of emotional impairment. Most impaired residents recovered and apparently did well. Seventy-nine percent continued in medicine.

(8) Ignoring self care, including not getting enough vigorous activity or real relaxation, eating too much food, drinking too much alcohol, smoking too many cigarettes, ignoring physical checkups, being unable to be sick and finally treating one's self — Selecting "personal friends" to serve as one's personal physician is a potential problem.

(9) Acquiring a spouse who is a superb caretaker may be very supportive initially, especially in medical school. Considerable difficulty may occur later as the physician moves into practice and no longer has a need for "mothering." — Similar problems may occur when the female spouse has children and no longer needs to "mother" a dependent husband. "Parent-to-parent" relationships, neurotic but stable unions, between two "save the world" personalities can put off intimacy, mutuality, sex and reciprocity. One couple said, "We haven't had a vacation outside of a medical meeting for 20 years." They eventually got tired of giving and started looking around outside the relationship to "get."

(10) The spouse is a source of stress when fostering the physician's being "special" and "omnipotent" — Further complications occur when the spouse protects the physician from telephone calls or when seen as an extension of the physician by the public. Even with the increased publicity of physician's problems, there continues to be a public expectation of the physician's spouse and children as models of virtue and brilliance, accomplishment and sacrifice. The lack of privacy of even the most intimate moment is interrupted by the telephone unless wisdom has prevailed and the plug has been pulled.

(11) Changing medical practice patterns in the United States — Regulation, bureaucratization and institutionalization hang over physicians as clouds marked DRGs, HMOs, IPAs, corporate medicine, managed care, preventive self-help and alternative professionals. These can lead to excessive testing or inadequate treatment leaving the physician anxious and frustrated.

(12) Life pattern changes — These include shifts from private to academic medicine or vice versa, from solo practice to group practice and practice geographic relocation. A major change becoming more and more common is retirement. The more heavily career-oriented the physician has been, the more stress potential the retirement. Retirement is simply a shift from one phase of life to another. A number of physicians I have seen have solved their retirement problem by moving from the clinical practice of medicine to institutional salaried positions or administrative functions.

Drug abuse and suicide are common among medical students, half of whom need psychotherapy, while a smaller number actually receive it. The physician suicide rate is two to three times that of the general population. Alcoholism and heavy drug use in physicians are half again that of a comparable non-physician group. Others report dissatisfaction with their work, marriages and sexual relations. Personal and social isolation from the medical and non-medical world may occur.

Tasks of the family are first, by and for the adults in the family and, second, autonomy for the children. Support is the development of a clear contract which clarifies commitments, individual goals, ideas and feelings. This enables effective decision-making for one's self and effective decision-making with other family members. This allows the necessary action for completion and for reflection in a shared, interactive fashion. Autonomy for the children is the provision of love, nurturing, mirroring and resources. Children who are lifelong dependents are significant stressors.

The following are specific recommendations for physicians:

(1) Take care of yourself and encourage members of your family to do so.

(2) Eat a balanced diet, cut out tobacco, minimize or cut out alcohol, caffeine and salt.

(3) Get vigorous activity at least three times a week and preferably every other day for a minimum of 20-30 minutes to provide cardiac training effect.

(4) Stay in touch and appreciate your feelings and those of each member of the family. Write down what you felt over the last 24 hours — when you felt scared, mad, sad, happy and what events were taking place at the time.

(5) Use "letting go" techniques such as relaxation exercises and deep breathing. Capitalize on your knowledge of the feedback system in your own body and practice body awareness.

(6) Make intelligent, positive decisions for yourself and with your family, based on goals. Address the question "How do I want to be?" Use single words or short phrases and examine current day-to-day life as it seems to relate to these goals and begin to take steps about each one of the goals each day. Share your feelings and your thoughts with your spouse, explore your spouse's feelings and thoughts.

(7) Encourage family members to have their own private physicians and provide no more treatment for yourself or for them than a lay person would.

(8) Learn to say "no" and keep priorities straight— "me first, family second, patients third."

(9) Manage your schedule — don't let it manage you. Structure and plan your time off — personal time, family time and fun time. Examine your schedule to see that it does include time for fun, weekly and perhaps even daily, that it does include at least 15 minutes of special time with the spouse and with each child.

(10) Get a personal primary physician and take your treatment out of your hands. Do not choose a "personal" friend.

(11) Spend time alone with yourself and individual time with your spouse and each of your children. At times it is important for the entire family to be together. Take the time to think about and share with your spouse and children thoughts that you have wanted to say, would want to say if you were no longer to be together through some accident, etc. Take non-medical-related vacations and leave your medical books at home.

(12) Be humble; we physicians don't know everything. We can learn a great deal from children and our patients. Listen!

(13) When providing medical services keep the patients, concerns and the resultant evaluation and treatment first and foremost.

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Beyond the River

*John T. Morris, B.S., M.D.**

The area of Alabama that the Cherokee Nation was forced to leave in 1838-1839, beginning the "Trail of Tears," is perhaps the fairest portion of the state. The old Tennessee River, after draining the splintered Appalachian mountains, sloshes into Alabama and deposits its good soil. After reaching Marshall county it seems to sense its mistake and turns back toward Tennessee. Near the point at which it makes its northwesterly turn, the great Hernando De Soto is said to have watered his horse. Here one finds the very best fishing. The mountains and forests abound with wild life: deer, bear, squirrel, rabbit, raccoon and opossum. Waterfowl pause here on their migratory missions, and the bald eagle fishes these waters the year round.

In this setting, in Marshall County, Alabama, "the most remarkable surgeon in history," John Allan Wyeth, was born on May 12, 1845 in a sturdy two-story log cabin that had been a Presbyterian Mission Station to the Cherokee Nation. The Mission Station was about three miles from the present town of Guntersville. While still in good condition, it was razed in 1930 and, due to the construction of the Tennessee Valley Authority Dam at Guntersville, the site is now under 20 feet of water.

During John Wyeth's childhood in Marshall County, the Indian trails were the only routes of commerce. Wagons and buggies were useless. Horseback and pack trains and single-file walking were the only practical means of travel. As a child John Wyeth grew strong and healthy on corn bread and "pot likker" fed to him by Aunt Peggy, the nurse and friend he loved. After Mack, the Negro servant, had taught him to ride, John Allan Wyeth practically lived in the saddle. Mack also taught him not to "get scared and quit." Young Wyeth hunted the game-rich woodland with his dog, Duke, and he swam and fished in the Tennessee River. His was a happy, carefree childhood. The climate was wonderful. Sickness was rare since the Cherokees had shown the white folks in the area the value of hanging gourds for purple martins to keep fevers away.

John's father, Judge Louis Weiss Wyeth, was wealthy by Alabama standards when he arrived from Harrisburg, Pennsylvania. He was a just and reasonable lawyer and became quite successful. He served one term in the Alabama State Legislature, meeting in Montgomery, and he was elected Circuit Judge of Marshall County, Alabama. He gave freely to local charities and worthy enterprises. He financed and built the first brick courthouse when Guntersville became the County Seat of Marshall County. He gave a plot of land to each religious denomination in the county, though they did not all choose to build on them.

But John Wyeth was not a recipient of his father's benevolence. Shortly after he learned to ride horseback, John began to earn his own spending money. He carried corn to the water-powered grist mill. He hoed the fields and cut and hauled firewood for the neighbors. He began his education at age five, with the daylights scared out of him in the very beginning. He found that during the previous term the schoolmaster had whipped two of the students so badly that the school's reputation for strict discipline had spread throughout the county. The older boys had told John to always drink plenty of water because the schoolmaster would whip the boys until they wet their pants. But when John registered, he found that the school board had replaced the infamous schoolmaster by a Mr. Dane, part Cherokee and all gentleman. He was mild mannered, but he had a long hickory switch standing in the chimney corner. It was only a reminder. He never used it. John liked this schoolmaster and learned well under him, but John did keep well hydrated.

One week out of school at Christmas and the months of July and August made up the vacation periods. During the fall and winter, John hunted and became competent in wood-craft and in the use of firearms. He roamed the woods barefoot, stalking rabbits, squirrels, ducks and geese. At the age of ten John owned his own gun and horse. The latter was a coal black mare with a white star in the center of her forehead, named Fanny.

One of John's early expenditures, from money he had earned cutting and selling firewood, was a subscription to *Harper's Maqazine* and *Harper's Weekly*.

*1316 Legion Drive NW, Cullman, Alabama 35055

An early treasure was a personal letter from one of the original Harper brothers. William Makepeace Thackeray was a contributor to *Harper's* at that time. *Harper's* was worthwhile reading and had a positive influence on the developing young mind.

John read from his father's extensive library, and he was taught by Professor W. D. Lovett, who had come from Zanesville, Ohio, a college graduate well-versed in the classics and an excellent mathematician. Lovett encouraged and inspired John. With Lovett's help and that of his father, John studied for and passed the college entrance examinations and entered La Grange Military Academy in Franklin (later Colbert) County, Alabama, at the age of 15, on February 1, 1861.

La Grange was a fine college with several lofty, neo-classical Greek buildings and a faculty consisting of some of the best educated professors in Alabama. It closed in December 1861, the faculty and the older students answering the call to the colors. Later, marauding Federal Troops completely destroyed La Grange Academy.

II

John returned home. He made a crop in 1861-62 and protected his home from the bushwhackers that the war had spawned. Louis Wyeth, while opposing secession and being over-age, nevertheless had joined the Confederate Army because of the tremendous love he held for his adopted state. He came back homesick and discouraged. The judge's legal training and sedentary occupation had not prepared him for military campaigning.

Now John, age 16, feeling it his duty to take up arms in his father's stead, went with General John Morgan as a "civilian independent" on a raid. Wyeth returned with a new horse, also named Fanny, and the reputation of a competent trooper. General Morgan advised John to join a regular army organization or he might be shot as a guerrilla if he got himself captured. John joined Company I of Colonel A.A. Russell's Fourth Alabama Cavalry Regiment in April of 1863. He spent $50 dollars on a six-shooter and a Burnside carbine.

With the Fourth Alabama Cavalry, John went into action almost immediately and fought in some engagement practically every day. He fought at Shelbyville, Morris Ford, and Winchester (Tenn.). In mid-September, 1863, his superior officers offered him "unlimited leave of absence" for "extraordinary bravery." He refused the leave and remained with his outfit and fought through the bloody three-day battle at Chickamauga Creek. The day after the battle, while the infantrymen were resting and burying the dead, Wyeth's unit, in a running fight, defeated the enemy at McLemore's Cove. After a few days of comparative inaction Wyeth fought in the engagement at Cottonport. Two days later he took part in an action at Anderson's Cross Roads, in the Sequatchee Valley, where his regiment took many prisoners and captured and destroyed the largest wagon supply train of the war. There were several hundred wagons loaded with supplies and munitions for the Federal troops in beleaguered Chattanooga. The burning wagons extended for eight miles along the road, and the smell of burning provisions tantalized the hungry troops under siege in Chattanooga.

For John Wyeth this was a hollow victory. The horse, Fanny, that he had captured on his first raid, threw a shoe and came up lame. He loved Fanny, whom he had trained to perfection as a war-horse. With her he had fought practically every day through some of the most bitter engagements of the fratricidal war. The Yankees captured John, riding a different horse, shortly after he lost Fanny. John spent most of the remainder of the war as a prisoner in Camp Morton, Indiana.

Life as a P.O.W. in either army was miserable. John entered the military in perfect health. Due to the crowded, unsanitary conditions of the prison camp, he contracted scabies, lice, and measles with superimposed pneumonia. This condition could have been fatal. He spent 16 months in this humiliating and sickening place. Years later, John would write about Camp Morton in an article published in *The Century* magazine. This article is a classic on life in a Federal military prison. The Confederate prisons were said to be worse.

In February 1865, more dead than alive, he was exchanged. Furloughed for 60 days he returned to duty and was recaptured in May 1865. This time his imprisonment was briefer. He was able to escape.

III

After the surrender of the Confederate forces in 1865, the South was completely prostrate. Union raiders and such renegades as the Jukeses, the Rains, and "old Ben Harris" had destroyed the cities and plantations of the Tennessee Valley. They had burned farm houses and farms that had been productive and prosperous. Chimneys now stood like gravestones over the tangles of weeds and briers. The raiders had killed outright many innocent civilian women and old men. Among the survivors, sickness and starvation

was rampant. After the second woman in Guntersville died of starvation in 1865, Louis Weiss Wyeth swallowed all his pride and boarded a train for the North. The Judge had grown up in the North and he knew the people of the North to be generous humanitarians. He stopped in Nashville, Tennessee, Louisville, Kentucky, Cincinnati, Ohio, and other places asking for donations. The generous response was gratifying. Food began to roll in by the train loads and Judge Wyeth set up relief stations in Marshall, DeKalb, and Blount Counties. These contributions tided the stricken area over until the crops of 1866 ended the famine caused by the war.

It took two years at home for John to recuperate after the war. He attempted farming in Marshall County, but finding that he could no longer do the hard physical work of the farmer, he decided to look at other occupations. He considered law, the profession his father had followed with such distinction. Law was not to his liking. He wanted to do things with his hands. He remembered the sickness in Camp Morton and the horrible treatment of the wounded during the war. Maybe he could improve on the practice of medicine. He was sure he could do better than the surgeons he had seen operating after the Battle of Chickamauga.



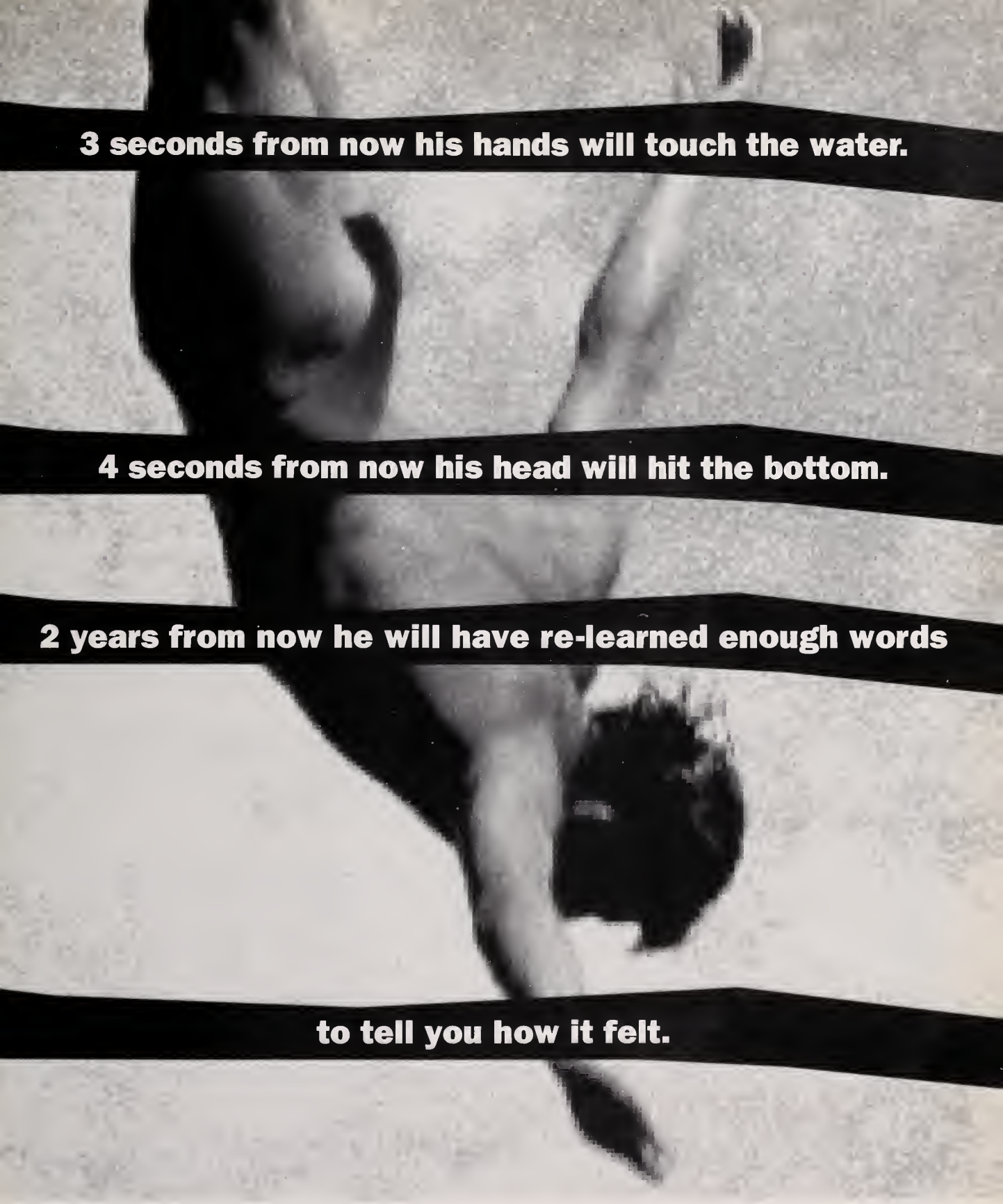
In 1867 John Wyeth matriculated in the medical school at The University of Louisville, Kentucky. He had practically no formal education, but he graduated, in 1869 after two terms, and was awarded an M.D. degree. He left the medical school with a pair of doctor's saddle-bags, diminutive apothecary scales, two forceps for extracting teeth, a set of surgical instruments, and a tin sign that read: JOHN A. WYETH, DOCTOR. He affixed the sign to the wall of his home in Guntersville, Alabama, one night in March 1869. John had no way of knowing that the year he began the study of medicine, in 1867, Lord Joseph Lister had launched the doctrine of immaculate cleanliness in surgery and before that Florence Nightingale had shown that cleanliness, fresh air and trained personnel were required for sick patients.

All Doctor Wyeth's training had been didactic. He had not seen any patients. He had not been inside a hospital. He fumbled through his first three cases, one a normal childbirth that delivered spontaneously. The fourth patient was a very sick diabetic who died. Nobody had expected the patient to live except Doctor Wyeth. He was despondent. (How could John Wyeth know that during his lifetime Banting and Best, using dog subjects, would discover insulin and a rational treatment for diabetes?). He left town (after tearing down the fine tin sign and throwing it into the well), intending to abandon the medical profession. At this precise time in his life, he realized the sorry state of medical training in America. He felt that he had been duped into believing falsely that he could heal sick people.

Wyeth spent three years in Arkansas, working as a railroad builder, superintendent of a cotton plantation, cattle buyer, steamboat pilot, land speculator and telegraph operator. Anyone who has felt the calling to practice medicine would know that John Wyeth, whom Mack, the servant, had taught to get back on the horse that had thrown him and "not give up," would try again. He arrived in New York City in 1872 for another try. Now his jaw was set. He knew what he wanted.

IV

Unfortunately, in October, 1872, the teaching of clinical medicine was not yet available in America's largest and most boastful city. Undaunted, Wyeth again matriculated in the freshman class of The Bellevue Medical School, and in 1873 he received from that institution a second M.D. degree. He remained on the faculty at Bellevue as assistant demonstrator of anatomy and then as prosector to the chair of anatomy and one of the instructors in that



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department, and he began his surgical practice. He never lost his vision of a school that would teach "hands-on-medicine."

Doctor John Allan Wyeth carried to the operating pavilion the same skills and artistry that made his Pennsylvania relatives, N.C. Wyeth and his son Andrew Wyeth, two of America's most famous painters. Dr. John Allan Wyeth inherited the gene for printer's ink from his grandfather, John Wyeth. The latter settled in Harrisburg, Pennsylvania, followed the printer's trade and served as president of Harrisburg Academy. In 1875 Dr. John Allan Wyeth published a *Handbook of Medical and Surgical References* and an essay on "Dextral Preferences in Man." He remembered the amputations he had seen as a soldier. Amputations of the foot were particularly unsuccessful in many cases. He felt that this operation should give the patient a stump that would bear weight and be functional. Too often, the posterior flap would become gangrenous and rot off, necessitating a reamputation at a higher level of the leg. Dr. Wyeth made anatomical dissections of more than 80 ankles studying particularly the blood supply. He found that there were several deviations of the arteries of the region and that the blood supply to the flap was compromised by most of the standard operative procedures, causing ischemia and resulting necrosis or rotting.

He published the results of his studies in 1876 in an article titled, "Amputation at the Ankle Joint." For this publication he received the Bellevue Alumni Association prize for, "the best essay on any subject connected with surgery or surgical pathology." The same year he wrote a "monograph on Minor Surgery." Wyeth's fame was spreading. He was becoming affluent. Following an episode of severe illness, he resigned his positions at the Bellevue Medical school, and during his convalescence, he decided to visit the famous medical installations of Europe.

In 1877, while touring Europe's medical centers, Wyeth met the greatest surgeon of the nineteenth century, a fellow ex-patriot from Alabama, Doctor James Marion Sims. Sims had known John's father, Louis Wyeth, when the latter was in the Montgomery, Alabama, Legislature. Sims was the only American doctor to visit Europe in the 19th century for the express purpose of teaching the Europeans. He congratulated Wyeth on the surgical essays he had written. They had long talks about medical education and compared the experiences both had had in their initial encounters with sick people. Sims encouraged Wyeth to work on his idea of an institution for teaching clinical medicine. Sims told John how he had raised funds for the New York Women's hospital, the first hospital exclusively for treating women. John Wyeth listened carefully to the older doctor, his admiration growing with each conversation. Undoubtedly, they discussed the proper management of hospitalized patients as postulated by Florence Nightingale. John met Sim's beautiful daughter, Florence Nightingale Sims, at this time.

In 1878, Wyeth was awarded the first prize of the American Medical Association for an essay on "The Surgical Anatomy and Surgery of the Carotid Arteries." He received the second prize of the same association, also in 1878, for an essay on "The Surgical Anatomy and Surgery of the Innominate and Subclavian Arteries." Employing the knowledge from Wyeth's dissections, Alfred Blalock, in 1943 did the first "Blue Baby" operations that opened the field of Cardiovascular surgery. Wyeth had shown that there was adequate collateral circulation if either the left common carotid or the innominate artery were ligated, but not both in the same patient. Knowledge of the collateral circulation of the carotid arteries made possible the operative procedures by Dr. Walter Dandy on the Circle of Willis at a later date.

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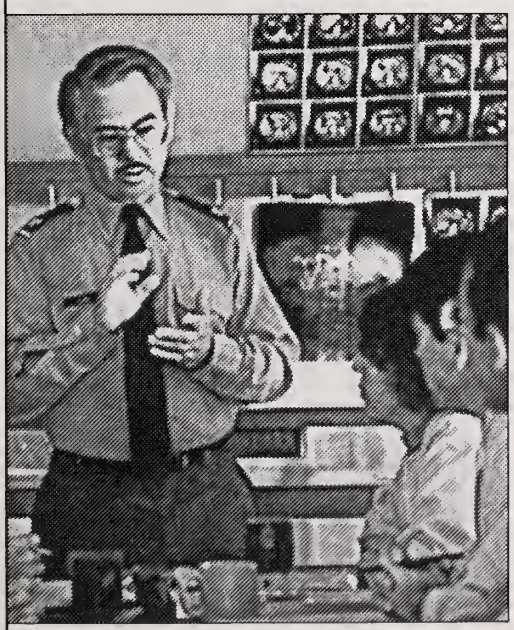
After visiting the great medical institutions of London, Paris, and Berlin, Wyeth returned to New York and in 1880 he was appointed visiting surgeon to Mt. Sinai Hospital and consulting surgeon to St. Elizabeth's Hospital. (Also, in 1880 Dr. Robert Koch established the science of bacteriology by demonstrating his method of growing bacteria on solid media.) John plunged into a campaign to raise funds for the hospital and medical school that he had been dreaming of for all those years. John's dream was of a hospital where young men (young women did not study medicine at that time) could learn to meet patients, talk with them, examine them systematically, do laboratory studies, get them in shape for surgery, operate and follow them through the postoperative period under the supervision of senior surgeons. John Wyeth believed this was the only way young doctors could learn all that the patient could teach him.

In 1881 Dr. Wyeth led the way in founding the New York Polyclinic Medical School and Hospital. Some pledged contributions did not come through and the undergraduate medical school did not materialize. Dr. Wyeth contented himself with concentrating on postgraduate education. This marked the beginning of formal postgraduate medical instruction, at the bedside of sick patients (internship and residency training), in America. This was, if not the chief, at least an important factor in the great movement that has caused the explosion of medical teaching and practice in America. Wyeth worked at the New York Polyclinic for 40 years, first as its Surgeon-in-Chief and later as president of the faculty. He published 75 surgical articles, each of which improved the clinical practice of surgery. New research was being done throughout the world. In 1884 alone, Crede announced that neonatal blindness could be abolished by placing one drop of silver nitrate solution in the conjunctival sac of the newborn child. Kohler introduced cocaine as a topical and local anaesthetic agent for eye surgery. Pasteur announced the prevention of rabies in dogs by vaccination with attenuated rabies virus.

Eighteen eighty-six was a busy year for Wyeth. He was president of the New York Pathological Society, an illustrious society that had numbered among its membership Francis Delafield, William Henry Welch and Mitchell T. Prudden. The first edition of his famous *Text Book of Surgery* was published. And, he married Florence Nightingale Sims on April 10, 1886.

The union was blessed by the births of three chil-

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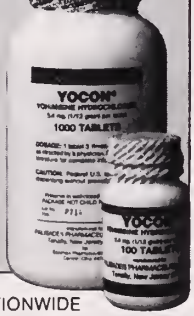
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dren: Florence Wyeth, Marion Sims Wyeth, and John Allan Wyeth, Jr. If Dr. John A. Wyeth, Sr. ever felt that he had been deprived of a formal education by The War, he never mentioned it. However, it is noteworthy that his children all received the finest formal educations available at the time. Florence Sims Wyeth graduated from Barnard College in 1909. Marion Sims Wyeth graduated from Princeton University in 1910, and John Allan Wyeth, Jr. graduated from Princeton in 1915.

Because of the discovery of the anaesthetic properties of ether by William T.G. Morton of Boston, and by Crawford W. Long of Georgia, Wyeth found that he could perform more and more sophisticated operations. Before antibiotics had been discovered by Sir Alexander Fleming, and before Pasteur and Koch had proved the germ theory of surgical infection, J. Marion Sims had prevented "stitch abscesses" by using silver wire sutures. Wyeth used his father-in-law's discovery. Wyeth did not have the benefit of Landsteiner's blood group and typing discoveries, so blood transfusions were not possible. In 1889 Wyeth reported work on "Bloodless Amputation at the Shoulder Joint" and in 1890 he reported his studies on "Bloodless Amputation at the Hip-joint" at the annual meeting of the American Medical Association. These operations received wide acclaim and were the forerunners of the "Radical Hindquarter" operation for certain cancers of the lower extremities.

Through his friendship with Henry Harper of Harper and Brothers publishers, Wyeth became a member of the exclusive Urban League of New York. He never ceased to care about his hometown in Alabama and its people. In the 1880's John Wyeth's father gave him a large tract of land in Marshall County, Alabama. John had this land laid off in lots by Albert M. Ayres and same of them were sold to northern investors. Several industries moved in and John named the town Wyeth City for his Father. Wyeth City operated many years with its own post office, school, baseball team and Temperance Society. It later became part of the city of Guntersville, Alabama.

Doctor Wyeth achieved many honors and many tasks were laid on him. He was professor of surgery and president of the faculty of the New York Polyclinic Medical School; President of the New York Pathological Society; president of the American Medical Association; president of the New York State Medical Association; president of the New York Academy of Medicine; and president of the New York Southern Society. As president of the latter organiza-

tion, Wyeth met Woodrow Wilson, a displaced Virginian, and urged him to run for president of the United States. Later, Wilson did run for president and Wyeth was his staunchest supporter.

In 1891 the second edition of *Wyeth's Textbook of Surgery* was published. It was an 887 page tome that covered practically everything known about surgery at the time. Many of the techniques and instruments described in it are in use today. It is beautifully illustrated by Dr. Henry MacDonald and very well written by Dr. Wyeth. With a few changes, deletions and addenda, it could be used today, 1993, one hundred and two years after its publication.

In recognition of his many humanitarian works, Dr. Wyeth was awarded the honorary doctorate of laws degree by the University of Alabama in 1900 and from the University of Maryland in 1908.

Dr. John Allan Wyeth was six feet tall, had blue eyes and brown hair. Marion J. Verdery said of him in an article published in the *Library of Southern Literature* before his death: "His bearing is so exceedingly modest that a stranger would never suspect his distinction. His sterling manhood combines with an exquisite gentleness of nature to make him kind, considerate, and generous. His heart is true to the impulses of sympathy and tenderness, his nerve is equal to the demands of highest courage, and his mind reflects the beauty of culture and the power of truth. His uncompromising integrity and exalted sense of honor harmonize well with the exactness of his science and the nobility of his profession. His character, as a whole, bespeaks the superiority of his lineage, and his brilliant achievements testify not only to his genius, but to the inestimable value o his conscientious labors for the relief of human suffering. High-minded, pure-hearted, and gentle-tempered, he commands confidence, inspires admiration, and compels love."

He would arise early and write, make ward rounds, and often operate before breakfast, but in later years he always planned a rest period during the day. He wrote on a vast variety of subjects other than surgery, mostly of his adventures as a youth in the Tennessee Valley and as a trooper in the War Between the States. He also wrote of his ancestor "Nathaniel J. Wyeth and the Struggle for Oregon," and, being a lover of the outdoors, he wrote several nature books and pamphlets including, "Trees in the South" and " Snakes of Alabama."

When young John Wyeth joined the fourth Alabama Cavalry, he met a group of hard-riding



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Alabamians who had previously served under General Nathan Bedford Forrest. These men never seemed to tire of talking of Forrest's kind treatment of them, his sympathetic nature as a man, his great personal daring, and especially of his wonderful achievements as a commander. Forrest spoke very good English. It is said that he once gave as his secret to military success: "Get there first with the most men." One of the Alabamians changed the wording slightly to the more famous: "Git thar fustes' wid the mostes." (I like my fellow Alabamian's version better). Wyeth admired the genius that he recognized in Forrest. They were kindred spirits in many ways. Wyeth carried to the operating arena the same spirit Forrest carried to the military arena. Wyeth made every effort to verify everything he learned about Forrest

John Wyeth's *The Life of General Nathan Bedford Forrest*, gathered from eyewitness accounts and personal knowledge, is the most accurate and meticulous source of information on that remarkable soldier, whose tactics and strategies have made many modern generals successful, among them: Field Marshal Erwin Rommel, General of the Army Douglas MacArthur, General George Patton and, most recently, General Norman Schwarzkopf. These successful soldiers must have read Wyeth's book, which went through several editions and was reissued in 1959 as *That Devil Forrest* by Harper and Brothers Publishers. *With Sabre and Scalpel, The Autobiography of a Soldier and Surgeon* published in 1914 may seem like the reminiscences of an elderly man (albeit an elderly man of clear retrovision). Three fourths of it are of his younger years in Alabama and of THE WAR. He skims over his great achievements as a surgeon, seemingly to avoid appearing boastful.

He died suddenly of a heart attack on May 8, 1922 and was interred in the Sims plot in Greenwood cemetery, New York, by the side of his wife, Florence Nightingale Sims Wyeth, who had died seven years previously.

The brick courthouse built by Louis Weiss Wyeth has not endured. A bronze bust of Doctor John Allan Wyeth, stands in front of the present Guntersville Municipal Building. He represents Marshall County in the Alabama Men's Hall of Fame. His fame extends far beyond the Tennessee River.

A colleague says this of Dr. John Wyeth: "He inspired the most profound confidence . . .he was like a ministering angel, always bringing with him an

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ACKNOWLEDGEMENTS

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The Year Ahead

It is my honor and pleasure to serve on the A-MASA Board for the 1993-94 year and to work for this unique organization. We are looking not only at changes in every aspect of medicine, but we are looking at the birth of a new auxiliary. The future of A-MASA as a viable volunteer organization will depend on our ability to change, to grow and to be flexible while retaining our heritage. We will be challenged this year to meet our goals.

Our first goal for 1993-94 must be to work toward a more active relationship with the medical societies of our state. We are truly the voice of medicine. Our greatest legacy to the medical community is our ability to extend our spouses' concern for their patients beyond the office and into the community. The endeavors of A-MASA and all County Medical Association Auxiliaries have a positive impact on the physician image, on the legislative arena, the area of litigation and the quality of life for others.

Secondly, as an active organization we must continue to offer programs and projects which promote health education, identify and address health care needs, encourage involvement in legislative education and support health related charitable endeavors.

Our third goal is to increase membership. We will recruit, orient, involve and reward and recognize accomplishments. We have strength in our ability to achieve a oneness of purpose and action. We have a strong membership of dedicated, concerned individuals who realize that what we do today, will shape our lives and health care tomorrow.

The fourth and last goal for this year is to remember that part of our challenge is for us to realize that for us to have the energy to provide leadership we have been given, we must first energize and motivate ourselves. I believe this is the finest organization with which I have ever been affiliated. Not only because as auxilians we contribute to our communities in a way few other organizations do, but because I also fulfill my needs. I meet other people, share ideas, information, work for common goals, learn and come away with new thoughts new friends and new energy. I go home to all my children, my wonderful husband and my business renewed and remotivated.

A-MASA is in a good position to meet all our goals.We are members of a leading volunteer organization in America. Our membership is working to show the people who will decide how health care will be delivered and medicine will be practiced, that the medical community is united on the issues that matter. Key among them is the well-being of physician patients and our community health care.

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The Art of Assisting

*Lee R. Nagendran, M.D.**
T. Nagendran, M.D.,FACS†

Just as one has to walk before one can run, a medical student or resident must learn to assist before trying to take on the role of the primary surgeon. Third-year medical students have made a tradition out of holding a retractor, yet rarely are they taught how to do so. Similarly, when the student advances to senior electives in surgery, obstetrics-gynecology, or other surgical subspecialties, no instruction is given as to how to first assist on a case. It is ultimately these skills as an assistant that will be perfected during the early years of residency, but assisting does not end here. Whether in academic or private practice, physicians are also called upon periodically to assist their colleagues in the operating theater. Therefore, the following guidelines are given to help prepare students for the role of the first or second assistant.

1. Always prepare for the case. Surgery schedules are usually available the afternoon prior to surgery. Most services also decide the previous day who will be assigned to each case. This gives the assistant ample opportunity to review the technique of the procedure, as well as the anatomy involved and possible complications that may ensue. If possible, get a good night's sleep and always eat breakfast the morning of the case.

2. Get to the operating room early. If you can, arrive at the operating room 15 minutes before the scheduled start time. This gives you the opportunity to review the patient's history and physical (presuming you did not do it yourself) and to double-check pre-operative test results. If you have time to spare, ask if the scrub nurses or anesthesia staff need any assistance. Remember that you are there to help in any way you can. After the patient is anesthetized and the surgeon arrives, help the surgeon prep the patient (setting up stirrups, for example).

3. Listen. Most surgeons recognize that students are not accustomed to assisting, at least initially. Therefore, they should explain what they want from you. Listen carefully, and if you do not understand what they are asking you to do, ask them to repeat it. Surgeons also teach by asking questions; do not get flustered if you don't know the answer. Many students have missed the same questions many times before. If you make a mistake in your technique, again, do not get upset. Acknowledge your error and move on. When the surgeon corrects you, listen carefully and make a mental note of what he or she has said. No one should have to tell you the same thing twice.

4. Anticipate. As you see more and more cases, you will find that you will have memorized the procedure in the more common cases. Learn to have the necessary instruments ready. If the surgeon asks for a silk tie, go ahead and ask for the suture scissors to cut. When he or she sees a bleeder and asks for the Debakeys, you know you will have to have the Bovie in your hand. A large part of anticipation is understanding what the surgeon is about to do and what the assistant can do to make his or her job easier. Therefore, the better you understand surgical technique, the better assistant you will be. This includes the retraction of any tissue that may be in the surgeon's way and aspiration of blood or fluid from the surgical field. Also, one should always make sure that his or her hands are not in the way of the surgeon's view of the operating area.

5. Be aware. As an assistant, you are able to pay attention to small but important details that the surgeon can't always worry about. Make sure that all the instruments that are not being used are returned to the scrub nurse. Clamp the suction when not in use, and clean the Bovie tip periodically. If the light is not in the best place for the surgeon, adjust its position using the sterile light handle. Also be aware of the sponges, needles, and suture being used, and where they are-this is extremely helpful when they are counted at the

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end of the procedure. The assistant should be always vigilant in making sure that vital structures are not in danger of being injured.

6. Follow up postoperatively. Always remember that surgery does not end with the procedure. Correct postoperative care is as important as the operation itself. As you read about possible complications before the procedure, you will be in a good position to observe the patient for any signs or symptoms indicative of problems.

Assisting in a surgical procedure is a wonderful learning experience. While it may be stressful the first few times, you will eventually become comfortable with the operating room. The surgeon will appreciate your attentiveness and help in the procedure, because it makes it easier for him or her to help the patient. And it may be that, when you become the attending surgeon, you will come to appreciate and enjoy having enthusiastic, interested, and well-trained first and second assistants.

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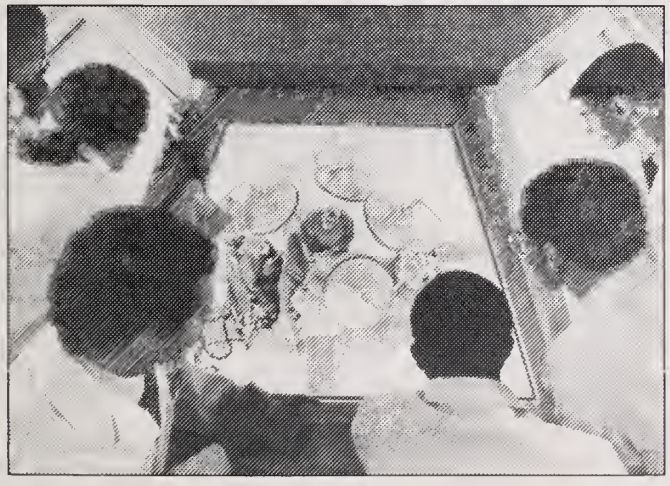
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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of child-bearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly it accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased it therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly it accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, penpheral neuropathy, penpheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticana, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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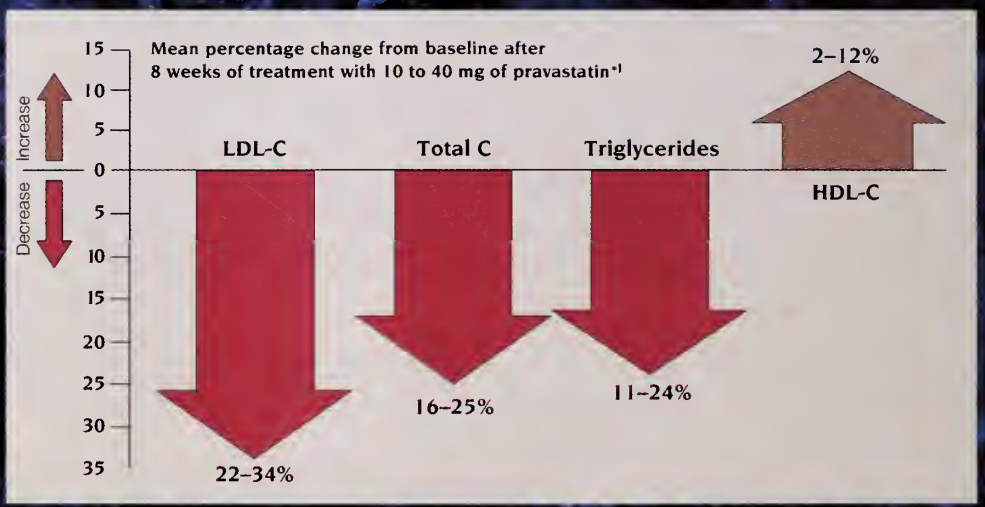
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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Thank You, Mr. President

By procrastination and decline in credibility, Mr. Clinton has helped restore sanity to the reform debate

-- Dr. West, p. 6

But Not you, Guru

Ira Magaziner's passion for complex central planning may have the opposite effect

--Mr. Conner, p. 2

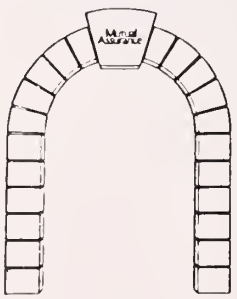
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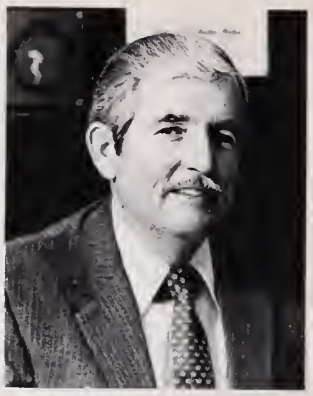
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EXECUTIVE DIRECTOR



S. Lon Conner
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Guru of the Paper Chase

As this is written, in mid-July, the most secret document in Washington was said to be the 200-page, densely packed, white paper on the Administration's health care reform proposal. It was to have been circulated to only a select few bigfoots in the Clinton Administration. According to reports, each copy had been secretly coded so that should one get in circulation, the culprit could be easily traced.

From the start, of course, the Clinton Administration has been obsessed with secrecy. The health care reform task force, presided over by Hillary, was as tightly hush-hush as any of Col. Ollie North's projects — or, for that matter, the Manhattan Project.

Although Hillary was task force chairperson, the guru-in-waiting was Ira Magaziner, who thinks big. Very big. Washington wags say that after he solves the health care problem, he will take on the United Nations, individually and collectively.

It has been charged and never effectively denied that the 500-member task force was assembled not so much to evolve policy but as tutors on health care matters for Mr. Magaziner, who was in need of a crash course on the subject before he set about reshaping it more to his liking. First and last, Magaziner is a central planner, an industrial policy nut and a man who thinks that the even the New Deal of the 1930s was kid stuff. But his career as a consultant for companies and governments reveals a grave flaw — overreaching.

During the transition, he made it known to then President-elect that he wanted authority over both health care and labor. Labor went to a rival, Robert Reich, who is no right-winger himself. Magaziner also coveted the top job at Commerce and the Council on Economic Advisors.

When those slots were filled by others, he was left with label of special assistant to the President, which sounded far humbler than what he had wanted to be, Emperor of Everything. Small wonder that some of the pundits inside the Washington Beltway are already predicting that health care reform will the nation's next Vietnam. Magaziner is an extremist theoretician.

Mr. Magaziner has made a career of revolutionary thinking, starting during his undergraduate days at Brown University. The status quo is always unacceptable to him. As a Junior there in 1969 he and a friend decreed that the school's curriculum put excessive emphasis on grades and was overloaded with requirements. They drafted a reform report that, after a year's debate, was adopted by the intimidated school faculty. The "new curriculum" remains wildly popular with students today. It's easy to understand why — the Brown reform wiped out virtually every requirement, from language to mathematics, reduced the credits required for graduation, eliminated the D grade and allowed Fs to be stricken from transcripts. Since Cs are now essentially Brown's failing grade, Bs can be had for little more than showing up.

All attempts to repeal the new curriculum and get back to educating have been beaten down by massive student rallies and threats of disruption. And yet, today, one of Mr. Magaziner's obsessions is the lack of standard in U.S. Schools. "We don't have any quality control," he has charged repeatedly, "we don't

know what we're getting for all that money we're spending."

Some have suggested that this statement is the thinking of many parents of current Brown students.

A couple of years after leaving Brown, Magaziner resurfaced in Brockton, Massachusetts, a down-at-the-heels suburb of Boston, famous only for having been the home of Rocky Marciano. When he arrived, Brockton was a foundering shoe factory town. Magaziner decided it needed total reform. He organized a frontal assault on the city's economy, set up a tenants union, a land trust, ran a food co-op, and organized consumer rallies. He also published a muckraking weekly newspaper, *The Brocton Examiner.*

He enjoyed some community support, since times were getting tough, but lost interest and left in 1973 without training any successors. His creations all withered away. There seems to be an object lesson here: he favors big, megalomaniacal undertakings but his love of the vast sometimes leads him into error by his cavalier attitude toward important details.

As a corporate consultant, he once talked GE into developing a new rotary compressor for its refrigerators instead of buying the compressor abroad as GE had been doing. That advice cost GE $450 million when the company had to recall a million of the compressors, which apparently had been designed and built much too hastily.

But it was in Rhode Island where Magaziner best demonstrated his affinity for flawed complexity. In 1982, at the request of Gov. Joseph J. Garrahy, he prepared a vast, multi-tentacled program designed to grow certain industries in the state and called the Greenhouse Compact. The working group he headed produced a massive, 1,100-page document. When the plan was unveiled, Magaziner had (typically) procured the endorsements of labor unions, church leaders, bankers, legislators, the chamber of commerce and the state's largest newspaper. For all the riches in industrial development promised, Magaziner had proposed, as seed money, a one-time tax surcharge producing $250 million.

Just about everybody seemed enthusiastic except for the entire economics department at his old school, Brown, and, as it turned out, approximately 80% of the people.

Magaziner had not addressed his sales pitch and his manic energy to the people who would have to pay for it. They blew him away after smelling the distant odor of pork. Just days before the vote on the plan, two leading Democrats in a notoriously corrupt legislature named themselves to sit on the ostensibly non-partisan commission that was to oversee disbursements from the venture capital fund. That was all the voters needed to know to reject Magaziner's complex proposal. They suspected fraud.

Mr. Magaziner was also responsible for President Clinton's support for a plan whereby every business, large or small, would be required to spend 1% of its payroll on training. Small businesses have protested that big companies could find a way to cook the books to fake compliance whereas small businesses could not and would thus be paying to train workers to be pirated away by the big corporations. Mr. Magaziner got this idea from Swedish socialism.

When you come right down to it, Mr. Magaziner and thus Mr. Clinton are counting heavily on U.S. small business to reduce the deficit and finance the lion's share of health care reform. Small wonder that the dynamo of the U.S. economy is gravely concerned about the impact of both on their fortunes.

Here is why placing small business at risk places the nation at risk:

Firms with fewer than 500 employees accounted for 10 million of the 18.4 million new jobs added in the 1980s boom. That's 54%. By contrast, the *Fortune* 500 industries *lost* 2 million jobs during the period.

The 90s have so far been very hard on small business, contributing to their nervousness over Magaziner's apparent belief that they are a bottomless source of revenue for the feds. For one thing, capital is scarce. One reason for that is that the government encourages banks to lend to the U.S. Treasury, by buying securities, rather than lending to expansion-minded small business. This is done by the regulatory agencies: banks must keep much higher reserves against loans to business than against loans to the government. Small business creates jobs by expansion. Expansion is fueled by capital. A capital shortage encouraged by Washington thus contributes to the employment shortfall.

But there are other anxieties. Small business will take an unknown hit in Clinton's budget plan. Beyond that, is the Administration's proposal for their "premiums" to finance health care not only for themselves but for the uninsured. They expect this tax, which is all that it is, to be in the range of 8% to 10% or more of payroll. Many small businesses would have no choice but to cut the payroll. The impact can be seen by looking at one company, Con Pac, a $20 million a year packaging firm with 220 employees in Texas, Louisiana, Georgia and Colorado.

At present, the company's total burden of workers' compensation, unemployment insurance, FICA, cost of compliance with federal regs, and so on, amounts to 33%. Com Pac provides tightly controlled health benefits for its employees. If the Clinton's succeed in adding 8% for health care costs, the 41% would play havoc with Con Pac's thin profit structure. The company has assumed a big federal hit in its decision to buy a $500,000 gluing machine to replace workers.

Hundreds of other small businesses right now are making similar decisions to opt for machines and automation to protect themselves from Clinton Administration taxes.

As this goes to press, national newspapers also report a sudden urge among highly profitable *big* companies to "downsize." Such companies as Raytheon, AT&T, and Proctor & Gamble. The latter after a year of record profits, announced in July that it was firing 13,000 workers. Why? Fear of the tab for health care reform?

Here is another example of the probable impact of the Law of Unintended Results. When all sources of revenue have been examined, after sin taxes have been taken into account, financing health care reform and reducing the deficit will require much more money. Some predictions are that the Clinton health care proposal may require up to $150 billion in new spending.

Soaking the rich won't raise that kind of big bucks. It will be necessary to place new burdens on the already threadbare middle class and on business.

As Mr. Clinton's guru, Magaziner has never shown much sensitivity to these groups except as cash cows. In Rhode Island he totally ignored those who would foot the bill. He may be all they say: a genius with numbers and in the manipulation of process. But he seems to have an academic elitist's indifference to the needs and fears of the working stiffs who are, in fact, the government. President Clinton has recently shown signs of the same infection.

In its deliberations on health care reform, as on the budget, Congress must give priority to weighing the ability of the middle class backbone and the small business job creator to shoulder the bill.

Otherwise, this may indeed prove to be America's second Vietnam.



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PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

Thank You, Mr. President

President Clinton may have made a greater contribution than he knows to sanity in health care reform. He did this, I think, by his procrastination in presenting a bill that was originally promised in the first 100 days of his administration.

Here in late July, there is still no bill although there have been dozens of speculations. After all, the options have been pretty well discussed for some time. And, as has been pointed out, there is not likely to be any significant proposal in his legislative package that is not already being tried somewhere. Many states are well down the road to "managed competition" and the private sector has years of experience in some aspects of the model.

Because of Mr. Clinton's repeated snafus and delays, the American public has cooled on the President. That is to say the enthusiasm the voters had during the campaign for his claimed ability to conjure up the free lunch has been dashed by the reality of his failures and by his seeming equivocation on almost every issue he faced with such bravado last year.

Public expectations for health care reform, dangerously high in the winter, have been constrained by one reality check after another. Slowly, as the months passed without the promised Administration reform bill, people began to get at least some small idea of the complexity of redesigning one-seventh of the U.S. economy.

Certainly the dimensions of this Herculean task must have impressed themselves on President and Mrs. Clinton. They must know by now that solutions are not quite as easy or free of consequences as they may have seemed on those New Year's bull sessions they have indulged in for some years. All problems look easy from the vantage point of distance and ignorance of the facts.

And the facts speak rather eloquently: the American health care system is the finest in the world; many Americans, while they may wish it were truly free care, have had second thoughts in the first half of the year about radical transformation that would (l) cost them significantly more in taxes than they had been led to believe; (2) result in a redistribution of resources that would adversely affect the care they now receive or confidently expect to receive in their hour of need; (3) deny them a true choice of physicians and facilities; (4) accept a lower common denominator so that all would enjoy the same basic benefit package.

As much as the politicians deny it, the public is beginning to realize that rationing is a necessary concomitant of any plan designed to be all things to all people. This is so because of the intractable debt we already have that will compel draconian frugality in any universal insurance program, among other reasons.

People have begun to understand, I believe, that this rationing may take two general shapes: qualitative and quantitative. They are beginning to see that both forms of rationing can result from cookbook, cost-analysis medicine that would place greater emphasis on spreading the wealth than on protecting their individual health and welfare. They are beginning to understand that restricting care can also be done by tiers of paramedical people, by economic triage, and by scores of other devices, including simple red tape (the "passive rationing" of World War II).

These awakenings are the direct product of the public's belated understanding that Mr. Clinton, for all his powers of persuasion, has not re-invented government, as he promised last year he would do, and cannot re-

invent a health care system that would be so efficient that all would be covered at no additional cost by "eliminating waste" and the excess profits of insurance companies and providers. That was his campaign promise, remember?

In short, Mr. Clinton's magic powers are being called into question by a public already contemptuous of government and government solutions. Just as surely, the public has come to comprehend, if only vaguely, that the American health care environment cannot be compared to that of Canada, or Britain, or Germany, or Japan.

Some facts that public may not yet know but should learn as the debate intensifies are these:

o The specious propaganda that compares life expectancy in this country unfavorably with that of other industrialized nations does not note some of the reasons: the 20,000 annual homicide rate in the U.S. is 10 times Britain's; that Japan has fewer than 300 AIDS cases. Nor do the propagandists mention that by age 80, when most people are most dependent on the health care system, Americans have the longest life expectancy in the world (7.1 years for men, 9.0 for women).

o The infant mortality rate in this country is skewed in the invidious comparisons by our heroic efforts to save low-birth-weight babies, efforts not always made in other countries, sharply reducing their "live born" data. The efforts of advanced neonatology in this country inevitably inflate our infant mortality figures in world comparisons for the simple reason that while many such babies are miraculously saved, many others cannot be.

Writing in the summer 1992 issue of *Health Care Financing Review*, Urban Institute scholars found that : "The more resources a country's health-care system places on saving high-risk newborns, the more likely its registration will report a higher IMR (Infant Mortality Rate)."

Nor does any other industrialized country have the number of drug-exposed babies we have, or the incidence of teen-age pregnancy, the absolute numbers living in poverty and squalor, or the carnage on the highways. Indeed, few industrialized countries have as high a rate of high-risk behavior of all kinds as this country does.

It may not be unreasonable to impute some of these factors to the failures of our society but it is distinctly unfair to blame all of them on our health care system. It is also foolish to contend, as many extremists do, that any universal health insurance program would cure these social ills.

Fortunately, while Mr. Clinton was pondering his re-invention of the U.S. health-care system, a few responsible voices have attempted to set the record straight. One of them was Fred Barnes, a senior editor of *The New Republic* and a reasonable conservative often seen on CNN's Crossfire.

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Writing in *The American Spectator* for May 1993, he asks, "What Health Care Crisis?" Mr. Barnes makes the point that since almost everyone gets some health care, in hospitals and emergency rooms, it is really an insurance crisis, not a health care crisis. As much as I wish his hyperbole were true, I am afraid this is a distinction without a difference. However, I emphatically agree with his conclusion:

"An overhaul of the sort Hillary Clinton envisions is not only unnecessary, it's certain to reduce, not expand, the amount of health care Americans receive (price controls always lead to less of the controlled commodity)....

"Will someone please tell Bill Clinton that having no health insurance is not the same as having no health care. The uninsured get health care, only less of it than the insured. Being uninsured means 'one is more likely to use emergency room care and less likely to use office, clinic or regular impatient care,' said Richard Darman, President's Bush's budget director, in con-

gressional testimony in 1991. 'This is not to suggest that this is desirable. It is not'."

Studies have shown that American hospitals provide at least $10 billion in uncompensated care annually; that 16.6% of the non-elderly population who are uninsured — some 36.6 million people — account for 11% of the nation's health-care expenditures. They don't see doctors as often or use hospitals as often as the insured, but they are not left totally unattended, as some unscrupulous critics have intimated.

Many people do have a health care crisis even if it is the result of an insurance crisis. But since somebody has to pay for the care they receive *gratis*, the effects are felt throughout the system in denial of insurance to high-risk people, in skyrocketing costs for the majority who are insured, and so on. All this is part of the "crisis" too.

What we do NOT have, and I hope the public is now beginning to realize that, is a system that should be scrapped simply because some Americans don't have guaranteed access to it. Long ago a great British statesman laid down this fundamental law for the Parliament in which he served:

"If it is not necessary to do something, then it is necessary not to do it."

I'd like to see that printed on one of the President's jogging T-shirts.

At this writing, there is still only talk of what he will offer in September, or whenever. Many of his own party in Congress balked at the White House demand that they use the August recess to trumpet the virtues of a plan they had not seen. That also suggests that they have benefited by the President's long delay; they have seen enthusiasm waning and anxiety rising among their constituents.

All in all, the time Mr. Clinton has squandered making up his mind has served our patients and our profession well, and I thank him for that. Had he produced his plan in January, when his popularity was high and his record of failures yet to come, our peril may have been far greater.

I do not mean to suggest we are out of the woods. Far from it. We have a long and treacherous path still ahead of us. For example, at the moment of this writing there are 86 congressional co-signers to a House single-payer bill. Congress is unpredictable on this issue.

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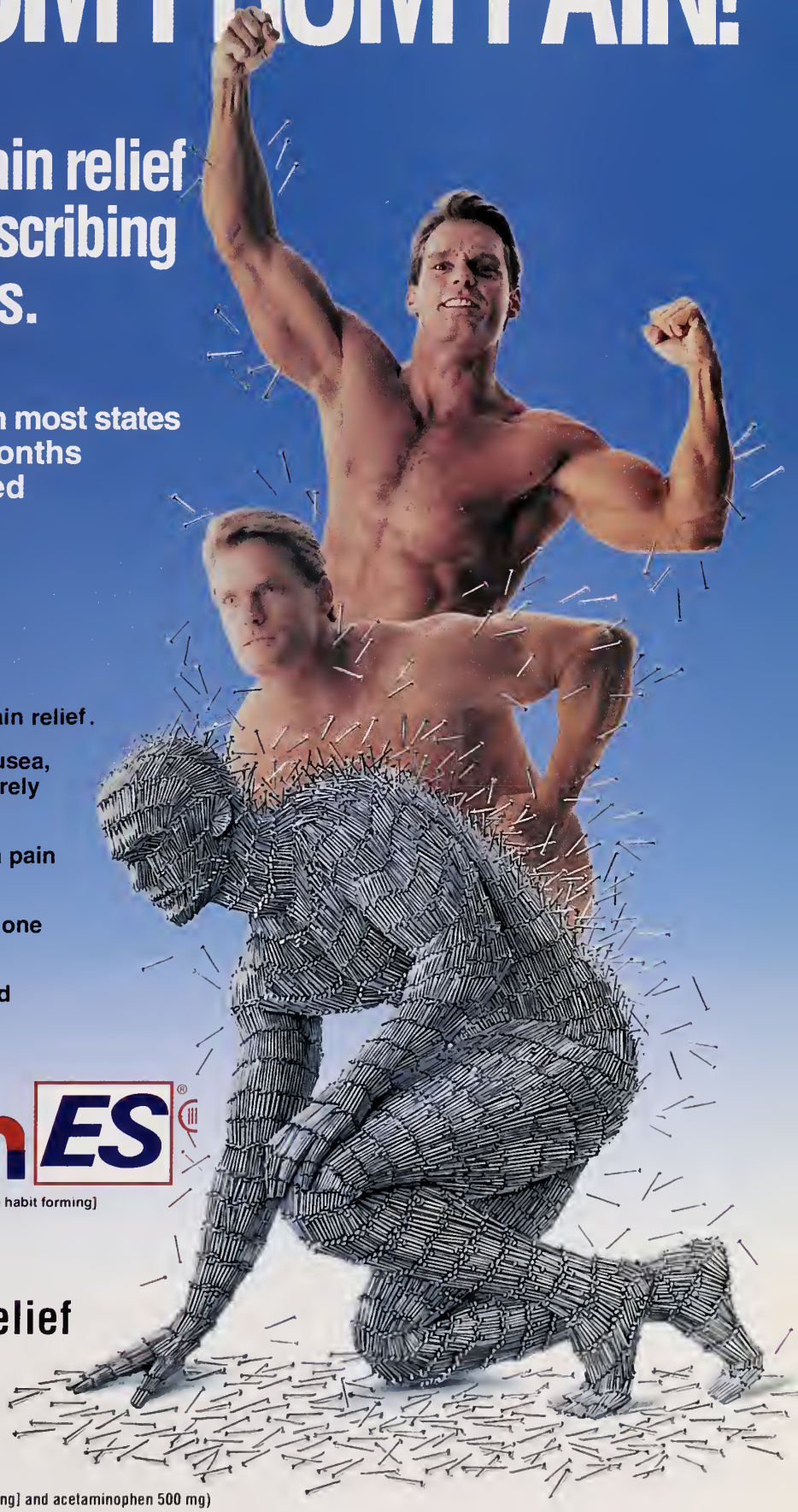
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These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: **Central Nervous System**: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes. **Gastrointestinal System**: The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. 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The Good Old Days vs. The Best Of Times

Stanley D. Hand, M.D.

Earlier this year [Feb. 28, 29, and March 1, 1993], I made a "Washington House Call" with the Medical Association of the State of Alabama, and later attended the "A Time for A New Partnership" [March, 23-25] in Washington, D.C. with the American Medical Association and sat for many, many hours listening to politicians tell us what is wrong with our present healthcare system, how bad it is, how all of the poor people are without medical care, and how it is time for "total reforms" of the health care delivery system in the United States. They also tried to tell us how good other systems around the world are working. As I sat there listening I could not help thinking about the times that were, the times that are, and wonder about the times that will be. What changes will the next few months and years hold for those of you providing health care for your patients?

Times have changed since 1948 when I graduated from medical school, and so has the practice of medicine. Had some farsighted professor in 1945, when I was a freshman in medical school, tried to tell his students that doctors would some day be able to pass small catheters into the arteries of the human heart and blow up a balloon to dilate obstructed arteries, or bypass obstructed arteries with a vein graft, or stop the heart from beating and keep the patient alive on a machine while surgery was being done, he would have been called down by the dean. Had that same professor tried to tell us that some day in the future we would see the time when "spare" human body parts would be in demand for transplantation to patients in need of those parts he would have been quickly put into restraints and carted off to the "funny farm." Yes, times and the practice of medicine have both changed drastically.

Why I happened to be one of those chosen few who just happened to be born at the right time to have been practicing medicine when the greatest advancements in medical knowledge, drugs and pharmaceuticals, equipment, and technology took place I do not know, but it has been a wonderful time to be alive. I was working for Doctor Albert Casey, pathologist at the old Jefferson-Hillman Hospital in Birmingham, back in 1943 when the first doses of penicillin were give experimentally in the State of Alabama. Patients then were given what was considered a big dose of some 50,000 units every six hours. Yes, things have changed.

Sitting in The Willard Inter-Continental Hotel and later in The Stouffer Mayflower Hotel in Washington DC again thought about old times and the wonderful times that I have had in the practice of medicine. When I hear doctors talking and writing about "The Good Old Days" I wonder if they are confusing them with "The Best Of Times", and I think that a clarification of definitions is needed. If we are referring to what medicine has to offer our patients, and what we, as doctors, can do for our patients, we are now living in "The Best Of Times". After listening to all of the political rhetoric in Washington and what the lawyers, the politicians, social welfare workers, and economists are planning for the future healthcare of the nation, I believe that the late 80s and the early 90s may forever be "The Best of Times" for medicine. Never before have we seen a time when our highly trained and highly specialized younger doctors can do so much for patients. Nor have we ever seen a time when technology has advanced so fast and made so many new diagnostic and therapeutic modalities available to the patients. These are truly "The Best Of Times," but, with all of these new found drugs, skills, technologies, and machines, we have lost some of the things that made for "The Good Old Days Of Medicine".

When were the good old days of medicine? For me, they started in the mid-fifties and extended through all of the seventies and even into the early eighties. Doctors saw the development of the wonder drugs, the antibiotics, and new vaccines, and with

them had learned enough to be able to prevent or cure many of the previously more or less untreatable common diseases. Many diseases that were rampart during my early practice like poliomylitis, diphtheria, scarlet fever, tetanus, whooping cough, subacute bacterial endocarditis, scurvy, and rickets will seldom and maybe never be seen by the young physicians of today. Many of the then more serious diseases like pneumonia, Rocky Mountain Spotted Fever, tuberculosis, gonorrhea, syphilis, and many other diseases could then be treated and cured by the new drugs.

What made "The Good Old Days" so good? Most of the outstanding advancements were wonderful, but for me it was the feeling that I was in command of the situation, be it my office, my practice and my patients or the hospital practice. I felt that I was in control of things, and that I really was the boss. Later in my practice I, like most of you, had lost control. I was told by the insurance companies and by government agencies what I could charge for my services. I was told by these same agencies when I could admit patients and when I should discharge patients. The hospital dictated when I would be on call for the emergency room and when I would be on call for in-hospital coverage. I no longer had control of my time, my life, or my practice.

Another thing that made for the good days was the patient contact, the time to sit down and talk to and with my patients, the mutual trust, the relationship with the patient and the families, and the financial relationship that made practicing medicine so much fun. It was fun beyond what most younger doctors can conceive. It was so much fun that many doctors would neglect their home life and their families for their practices. I know that most of you find it hard to believe that making house calls in the middle of the night, or having to work over in the office for two or three hours in the evening, or putting in 12 to 14 hour work days could possibly be fun, but it was.

Too, let me make clear the financial arrangement that most physicians had with our patients, and how it worked. In a small town of six thousand people where

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I started in practice all physicians were doing general practice and knew most of our patients by their first names. We knew their families and what they did for a living. I knew how many children my patients had, how hard they had to work to make a living and how well they managed. After an office visit every patient got up and, before leaving my office, asked me how much they owed me. This gave me the chance to make any adjustment in my charge that I felt needed or deserved. Many patients left my office with a "N.C." on their ticket. There were no third parties involved, no insurance forms to be completed, not a lot of billing to be done, and most doctors did what we called our fair share of charity work. I worked on my patients, for my patients, and looked to them for my pay, and I found it impossible to lie to, over charge, or knowingly mistreat my patients.

Another thing that made the good old days so good was the respect, the trust, the confidence, and the esteem that patients had for their doctors. In cleaning out my office when I stopped practice I found one of my first malpractice insurance contracts. Would you believe $174.00 for a year's coverage for obstetrics, surgery, orthopedics and everything? Patients did not question or doubt the doctor, nor did they want or ask for a second opinion for everything. Two and a half years have passed since I stopped seeing patients and many still call me to chat or ask for my opinion or advice .

After five days in Washington I am convinced that the practice of medicine as I have known it, and as those of you in practice today know it, will soon change to a system that many of you will not like, enjoy, or even find to be tolerable. Healthcare reforms are on their way. You will soon be hearing more about "FairShare Healthcare," "Health Access America," "Americare," and many, many other healthcare plans, but none of which will be called "Socialized Medicine," You will also be hearing reference to many legislative proposals such as, global budgets, health care networking, managed competition, managed care, employer mandates, cost containment,

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Some interesting facts that came out of the Washington meeting revealed that in 1991 the Americans spent $751.8 billion on health care. For each health care dollar spent: 38 cents went for hospital care, 19 cents went for physicians care, 8 cents to nursing homes and drugs, and 6 cents went for administrative cost. Out of each health care dollar paid: 33 cents was paid by private insurance, 16 cents by Medicare, 13 cents by Medicaid, 14 cents by other government programs, and only 19 cents out-of-pocket.

There are three categories of people in this country. Some people make things happen. Some people just watch things happen. Some people wake up and ask, what happened? We need to make things happen or we may wake up and want to know what happened. Start by calling and writing our congressmen today, or better, visit them and talk to them. You only have three people in Washington that care what you think or what you want, and they are your two senators and the one representative from your district. Contact them by phone, by letters, or, better, by personal contact.

Now is also the time to get behind your State Medical Association and the American Medical Association and their officers. You may not like everything that they are doing but, like it or not, organized medicine is the best thing that you have going for you. Get with organized medicine today and at least be a part of planing the future of medicine or "The Good Old Days" may be forgotten and "The Best Of Times" for medicine may forever be the yesterdays of medicine.

It is not to late to do something, but do it now.

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Liability and Physician Impairment

Address to the 1993 Intemational Conference on Physician Health

Raymond Scalettar, M.D.
Chair, Board of Trustees
American Medical Association

π The following message from Raymond Scalettar, M.D., Chairman, Board of Trustees, American Medical Association, was presented during the International Conference on Physician Health in Scottsdale, Arizona, January 28-31, 1993. The message emphasizes the AMA policy urging that "physicians engaging in patient care have no significant body content of alcohol" prior to being available for patient care. The report shows that the AMA has keen insight into the inequities of the legal system when dealing with the impaired physician. The frustration among American physicians over legal hassles and escalating paper work is fully recognized by Dr. Scalettar. "Paperwork actually distances us from the people we are trying to serve." Dr. Scalettar's message is timely and reassuring that the AMA recognizes the dilemma physicians feel. Recognition of the problem is the first step in its resolution.

Gerald L. Summer, M.D.
Medical Director
Physicians Recovery Network

Good aftemoon. I am so honored to be part of this conference. Your emphasis on physician health is — well, it's healthy! Healthy for physicians, for patients, for the whole health care system. And your focus on so many different aspects of physician health is healthy, too. I've watched with great admiration as the scope of these conferences has moved from physician impairment to physician health, has widened to encompass the health of physician families, has broadened its scope to injured, ill and aging physicians. And I'm very impressed at how this conference is turning the spotlight on abilities — putting capabilities higher than disabilities, accentuating the positive and inspiring hope. Now, my topic this aftemoon is another term with its root in ability —liability. "Liability and Physician Impairment" to be exact.

My practice is in Washington, D.C., right in the city. And being from the nation's capitol, the idea of relating liability and impairment brings to mind the so-called "Deaver defense." You may remember that when former Reagan chief of staff Michael Deaver was questioned about influence-peddling after he left the White House, he demurred that he had been having alcohol-induced blackouts at the time. He reasoned that since he just didn't have any recollection of the alleged abuses, he shouldn't be held accountable. Well, of course, the Deaver defense is no defense at all. And in fact, when it comes to professional liability coverage for physicians, most professional liability insurance policies explicitly exclude coverage of insured physicians if they practice medicine while impaired by alcoholism or drug abuse. And a physician proven to be under the influence of illegal drugs would also be excluded from coverage. Now I don't need to tell anyone here that when we talk about impairment and disability, we're talking about two very different things.

As a point of interest, the Americans with Disabilities Act states quite plainly that employers may not discriminate against a disabled person because of that disability, but employers do have a right to require that employees not be under the influence of alcohol or other drugs while they are performing their jobs. Signed into law in 1990, the ADA is one of the most sweeping civil rights measures enacted in decades. Right now, the AMA is seeking to clarify the application of the ADA to hospital medical staff credentialing procedures. Although it is clear that physicians who are employed by hospitals are covered by the employment section of the law, what about, say, a physician with privileges at a hospital who is not a hospital employee? Well, that is a somewhat murky area, as many provisions of the ADA are murky. And, it may take judicial action to clarify them.

What about a physician who drinks alcohol while

on call? You know the scenario. A surgeon goes to a dinner party, drinks one cocktail, eats a hearty dinner, sips a glass of fine wine. Then, suddenly, the pager goes off. There has been a huge highway pileup, and the surgeon rushes to the hospital to operate on several crash victims. Everyone in the surgical team smells liquor on the doctor's breath. But the surgeries go well. None of the team has any complaint about the surgeon's performance. And there's no problem. But what if a patient died? Then, potentially, there could be a problem for the hospital as well as the physician.

Well, the AMA has policy urging that "physicians engaging in patient care have no significant body content of alcohol." Further, we urge, "that all physicians — prior to being available for patient care — refrain from ingesting an amount of alcohol that has the potential to cause impairment of performance or create a hangover effect." The AMA is not a legal body, so we can only urge. But having this policy on the books sends a strong message to physicians. And it puts us on record against trying to combine alcohol and medical practice.

The AMA also has a policy about reporting colleagues who are impaired, incompetent or unethical. We urge that impairment be reported to the hospital's in-house impairment program. And if there is none, to "either the chief of an appropriate clinical service or the chief of the hospital" or to "an external impaired physicians program." In my own experience, this policy is followed quite successfully, though I know there's some public misperception that physicians protect each other and do not report such problems. In reality, impaired physicians do get reported, especially in a hospital or any other institutional setting. It's possible that physicians in private office practice may fall through the cracks when it comes to detection, intervention, and ultimately, rehabilitation. But, otherwise, I think the system of peer reporting is pretty strong. It's a system that emphasizes rehabilitation, not discipline. Health should always be our prime professional concern. And I'm proud to say, it's always been the concern of the AMA. In fact, the AMA first listed alcoholism as a disabling disease nearly 40 years ago. We've long urged impaired physicians to seek help — preferably on a voluntary basis. And we've long said that sanctions, license revocation and discipline should be used only when necessary, because our first goals are always treatment, corrective action and rehabilitation. Health. Ability. Capability.

Certainly — sadly — discipline is sometimes the only course. When that happens, the physician community must take responsibility for protecting the public as so many of the best physician health programs and hospital peer review programs do. On the subject of peer review, a 9th Circuit Court of Appeals decision late last year has given new validation to hospital peer review programs. It was a case which interpreted the Health Care Quality Improvement Act. A physician was stripped of his hospital credentials as a result of a hospital peer review action. He sued that this was a violation of Anti-Trust laws. Both the lower and appeals court upheld the peer review decision. They found that the hospital complied with the law and therefore was immune to Anti-Trust regulations. This 9th Circuit case is very good news for medical professionalism. Good news for peer review. Good news for professional self-regulation which is a big part of making sure that impaired physicians get help or get out of medicine.

Here's some news that's not so good. News about the relationship between liability and disabilities that do not cause impairment. As you know, disabilities do not necessarily lessen a physician's ability to practice medicine. But they may be perceived to do so. For instance, the AMA attomeys have told me about a particular malpractice case that was settled out of court because the defense attomeys decided the defendant would be an unsympathetic witness in the eyes of a jury. The reason: that physician had MS. And the lawyers determined that the physical manifestations of his illness would "turn off" a jury. The attorneys didn't think this was right or fair or understanding. Yet, based on their knowledge of what prejudices juries for or against a defendant, they thought it was realistic. And they may well have been making the right call in their client's best interest. But we can see, it's a sorry reflection of Americans' awareness that disability doesn't mean a physician lacks ability or is guilty of liability.

Various studies show that a small number of physicians are involved in a large percentage of malpractice claims. Ralph Nader's "watchdog group" Public Citizen has stated that most state licensing boards focus attention on physicians with drug and alcohol problems. Public Citizen suggests these are "easier to define and identify than incidents of negligent conduct." I don't think they have any evidence to support this contention, but we've all heard that "perception is everything."

No matter what the public may perceive, there is really very little data linking liability and physician impairment. One unpublished study looked at some 2400 closed claims cases and found impairment was an issue in only four. Four out of 2400. That's .016 percent! The author of this study told an AMA attorney he thinks the reason he has not been able to get this study

published is that it does not support the "conventional wisdom" — the perception that lots of negligence is caused by physicians with disabilities. Since there's no data to support conventional wisdom — or to refute it, either — we've just got to get a better data base if we ever hope to know what, if any, relationship there may be between liability and disability.

One thing we do know for sure about liability is the American professional liability system is a malpractice mess. The Rand Corporation estimates claimants receive only 43 cents of every dollar spent on medical liability litigation. And what's even worse than this fearsome financial fix, when you practice medicine under the threat of being sued, it's mighty hard to keep the professional satisfaction and personal joy that is so important to quality medicine.

In 1990, an AMA study of physician opinion on Health Care Issues indicated one third of all American physicians believe they might be sued for malpractice within the next year. That's pretty disturbing. And add to this kind of pressure the fact that so many physicians are bumed out from the hassles and tension of our health care system. And there is such frustration among American physicians over the high level of needless "hassles" that get in the way of our relationships with our patients. I'm talking about hassles like:

•Utilization review requirements that are cloaked in secrecy and weighed down by reams of forms and reports.

•Bureaucratic underestimation of the "art" involved in the art and science of medicine.

•Anti-Trust rules that hinder us in policing of our own profession as with fee gouges and, of course, just plain old paper work.

Consider that just in terms of medical insurance, there are about 450 types of electronic formats and more than 1000 types of paper forms. Paperwork actually distances us from the people we are trying to serve. Patients don't want distanced doctors. Good doctors don't want to be distanced from their patients. When we're distanced, we are more apt to be sued, as shown in the Physician Insurers Association of America studies, among others. And when we're distances from patients, and overly stressed, we're more prone to physical and emotional ills ourselves. So this is a very circular, all-encompassing problem.

Now let's take a quick look at what the future holds for reform of the professional liability system. Last year, 28 reform bills were introduced into Congress dealing with the subject of medical liability reform. Many were components of major health system reform proposals. Quite a few dealt with patient protection and physician disciplinary reforms. For example, bills introduced into both the Senate and the House would require that in order to receive Public Health Service Act funds, a state must certify that it requires each liability insurer to establish a risk management program and requires insured physicians to participate in those programs as a condition of maintaining their insurance. These bills would require states to contract with state or county professional societies to conduct peer review of medical liability claims, allegations and actions. And they would require the societies to preserve confidentiality, provide expeditious review and report their findings to the state disciplinary agency.

Confidentiality brings us to the future of physicians disabled by HIV infection. Or what about physicians infected with Hepatitis B? The Aerospace Medicine Association has stated its concern that cognitive loss due to HIV disease might be hard to detect, and, therefore, they don't think HIV-positive physicians should fly, but most neurologists disagree.

So far, we can't point to any liability cases connected to either HIV or Hepatitis B. Perhaps this is because the medical profession has been so careful always to put patient protection above all else while at the same time encouraging collegial responsibility. We know that physicians with medical conditions from epilepsy to HIV disease, just like physicians in addiction recovery, may find it very difficult to be hired if they do share information about their condition with a potential employer. And yet, they may leave themselves wide open for discipline if they do not.

That's why our Physicians Health Foundation is so important, and the AMA Physicians Career Resource, which offers consultation to physicians with disabilities, our placement service, which is free for AMA members. And the book *Leaving the Bedside: The Search for a Nonclinical Medical Career* published last year by the AMA is a guide for physicians considering non-clinical career opportunities in and outside of medicine. And it offers employment suggestions for physicians with medical problems.

Something else about the connection between liability and impairment. Speaking from personal experience, as I'm an officer with our own liability company, I can't remember a time we were called on to make a coverage decision about an impaired physician except in cases where recovery was working. I think that speaks well for the positive emphasis the AMA has tried to foster for so many years — the positive attitude represented by this whole conference.

Before you begin your very busy afternoon, I'd like to compliment each and every one of you here on your participation in this conference promoting physician health so physicians can live productive lives, contribute to our patients' health and healthily practice the profession we love. I'd like to urge everyone here — whether you're a physician or not — to make sure you have your own primary physician you're going to for checkups. A physician who's treating you like a patient, watching out for your health, alerting you if you need special care. I say this because, until five years ago, if someone asked me who my primary physician was, I'd have to say, "It's Ray Scalletar!" But my participation in our insurance company, and in organized medicine, and in peer review, helped me step back and take stock, learn to pace myself, get myself a primary physician and I'm glad I did. Knowing that we are patients as well as physicians, that's a big part of physician health. I hope with all my heart that physician health is the wave of the future.

In closing, I know you've all heard the old joke that M.D. really stands for "Massive Denial." Well, I remember maybe 15 or 20 years ago I was just horrified reading a Washington newspaper interview with a prominent Maryland surgeon. He was justifying how he could have two drinks at lunch and then go back to the hospital and do surgery because, he said, the alcohol had metabolized. I don't know what happened to him, but he was a glaring case of massive denial! And you know what? I don't think that kind of thing could happen today. Society as a whole is more aware, and the medical profession in particular is more aware, much more aware that people can live productive lives in recovery from addiction diseases. More aware that physicians have just as much right to care and compassion and respectful treatment as everyone else. More aware that disability shouldn't be allowed to obscure ability and capability. And each of you here is a big reason for the change. It's change for the good. So, keep up the good work. And, thank you.

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Public Health: Yesterday and Tomorrow

*John R. Wheat, M.D., M.P.H**
Jerry T. McKnight, M.D.†

Historically, public health in the U.S. was a state's response to protecting the general public from harmful, often epidemic, diseases through sanitation, control of communicable diseases, and providing health education.[1] In addition, the federal government provided direct medical care to special groups such as merchant seamen.[2] In the course of studying epidemics, public health developed the ability to measure various aspects of community health, and identify populations at particular risk for poor health. It is now public health tradition to identify high risk groups of people, such as poverty-level women and children, and assure they receive adequate health care enabling the health of the entire population to be preserved. Public health is also expected to protect the general public against adverse environmental conditions.

Out of this history, our current public health policies have evolved. The function of assurance of adequate health care led to public health's provision of primary medical care for populations that could not otherwise receive such care. This policy is not a crisp one because the line of demarcation between populations that can and cannot otherwise receive primary care is unclear at best and shifting constantly with changes in the economy, in private physician's personal practice policies, and in political ideology.

As we enter the next era of public health in Alabama, it seems appropriate to review these traditional public health functions in light of the current social environment:

1. *Sanitation* to assure safe water and food supplies and to remove human waste is observed to be inadequate for some Alabama families that live in poverty conditions. Recent reports show that Alabama's four largest cities and its rural counties have many families at risk by virtue of poverty. Because the poor health that is associated with inadequate sanitation often leads those at risk to use publicly funded health care, there is an economic as well as ethical basis for Alabama to invest in assuring adequate sanitation. Public health should document the presence of poor sanitation, identify individuals at high risk, provide these data to federal, state, and local governments and participate in strategies to reduce the risks. Inspection of food, water, and environmental conditions is a major part of this public health activity.

2. *Communicable diseases* responsive to immunizations and medications are well controlled by public health measures and there is a need to maintain vigilance in this area. However, the greatest communicable disease threat comes from diseases controlled by human behavior: AIDS and sexually transmitted diseases (STDs). These diseases are particularly prevalent in impoverished populations or those with low educational levels, and the costs in human suffering and medical care are high. The Alabama Department of Public Health has a well-recognized ability to monitor AIDS and STDs and predict populations at high risk for these diseases. Public health should use these data to stimulate strategic planning to deal with behaviors that spread these diseases and to care for persons sick with AIDS and STDs at local and regional levels.

3. On a state level, *health education* is best accomplished by a continuous appraisal of the population's health status, pointing out factors that contribute to poor health, and suggesting useful methods to lower the incidence of these factors. However, for illness associated with adverse lifestyle behaviors (e.g., heart disease, certain cancers, AIDS, and infant mortality), local actions will be required to gain voluntary changes in the reduction of health risk behaviors. Public health has a role in working with local organizations to develop effective health education programs for problems in the community. Family planning is an example where public health's role is well established.

4. In Alabama, with so many people living in or near poverty, there should be a mechanism to assure *access to adequate medical care* for the poor and

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underinsured. Often, medical care services are not available in communities simply because a physician cannot afford to practice there. In other communities, physicians may limit charity and even Medicaid care in order to retain a viable practice. In both circumstances, the poor, uninsured, and underinsured face decreased access to care. Public health has a role in assisting these communities in obtaining medical care for their citizens. This role is not a simple one, because there is much at stake in how medical care is provided. Medical care dollars provide strong support for local communities in their economic development.[3]

Therefore, public health should work with these communities to bring resources that help provide this medical care, and concomitantly maximize the opportunity for local economic development. This may mean providing data to document the need, leading local strategy sessions with community and medical leaders, and endorsing plans for health care provision for the medically underserved. In some cases, this may mean public health directly providing primary care. In others, it may mean collaboration in attracting public funds to help local physicians provide such care. The results should be a public and private collaboration to meet the needs of people and to stimulate local economic potential.

The situation may exist in which physicians begin practicing in an area where public health providers had been "filling the breach." When this happens, third-party payments for this care will be withdrawn from public health. The dollars used for local public health efforts (medical care and other functions) will be diverted to support physicians and correlated economic developments such as a pharmacy, hospital, or new medical services. What may be lost to the community are those essential public health functions that third party payments had helped support. Hence, public health will need the collaborative support of the physicians to secure public funding for these essential health activities such as environmental inspections, family planning, communicable disease control, and sanitation.

5. To the extent that *environmental conditions* affect the health of the population, public health must be involved. The data concerning many chemical hazards do not support the contemporary outcry for environmental purity. Nevertheless, there are some well recognized toxins that must be regulated for the good of the public. Public health should monitor the health of populations exposed to environmental hazards and toxins to detect ill effects. It should work with industries and agencies to see that exposure limits are maintained. It should participate in discussions of policy about environmental health by bringing population health and exposure data to the table along with health expertise.

In the foregoing discussion, we have tried to point out public health's role cannot be separated from economic, educational, and political conditions of communities. In fact, public health's role exists to a large part because of these factors. At the community level, public health should be coordinated with and supportive of efforts to improve these conditions as well as to meet individuals' health-related needs. Public health should always maintain the capability to (1) monitor population health and access to medical care and other health interventions, (2) point out unmet needs and inadequacies in services, and (3) participate in planning local responses. This response may include public health providing needed medical care or may include bringing public resources to support local health care providers, thus allowing these providers to extend their services. Schools, hospitals, doctors, employers and other local agents must be factored into local public health equations.

At the state level, public health should function to help local health departments in the tasks noted above. Providing data and analysis is essential, as is advocacy for needed resources. If communities develop strategies to address unmet local health needs, state level public health should assist the communities with these plans. The state level public health system that is most helpful will understand and relate well with the governor's office, legislature, physicians, federal public health programs, insurance agencies, Department of Education, medical and health related schools, Alabama Department of Economic and Community Affairs (ADECA), and other major helping agencies and interest groups. Thus, the state public health agency will be in a good position to facilitate state-level discussions that lead to support of local efforts.

The relationships between various interest groups, agencies, and the state's public health office are too many and too complex to be invested in one person. The board of health should develop the range of vision, expertise, and interest to maintain these relationships and forge policies that reflect the considerations from these many arenas. For example, if expert knowledge in economic development and in ADECA's role is not present, the board should work to acquire this knowledge. The same applies for expert knowledge about education at all levels, insur-

ance, legislative affairs of public health, governor's liaison, and the like. Such a broad-based board could forge policies that enable the state health officer to help communities meet their public health needs and increase local vitality.

Questions that arise involving public health would best be addressed by the broad-based structure suggested. Should there be a competing role between the public and private sectors? Should the role of the public health department be expanded or contracted? Should the health department take the lead role in the current AIDS epidemic and should legislation be enacted to allow the health department to trace sexual and drug contacts of HIV-infected patients, thus allowing the health department to make an impact? Should the health department target certain diseases (e.g., hypertension) and certain problems (e.g., adolescent pregnancy) for priority?

We believe the public's health may best be served by an integration of public and private sectors at the local level. By combining the strengths of both, a better use of community resources will be accomplished. The public health department should complement private physicians and help make their jobs easier; and we believe the reverse should also be true. In some cases, there may be a consolidation of public and private health forces. As health care resources are limited, we feel this cooperation is imperative. The physicians of Alabama should have a continued role in setting these parameters, because being on the "front line" gives them a unique perspective of the health care needs of the people of Alabama. Whether there is an expansion or contraction of the health department's role should be determined by an assessment of Alabama's health care needs. There is a continued role for targeting specific health care problems and the health department is in a unique position to perform this task.[4] The health education role of the health department is a continued vital need which should be expanded. The specific areas targeted for education should be appropriately defined to maximize success.

Continued strong integration of the role of the Alabama Department of Public Health and local health departments with other agencies of health and medical care is suggested to help meet our state's health care needs and strengthen our communities. Appropriate modification, redefinition, and refocusing of these roles will ensure future success to help achieve the goals of public health's mission. Often, such revisions are difficult, but we feel the local community provides the optimal setting for physicians, public health workers, and community leaders to make decisions that will best promote community vitality and improve the overall health of the citizens of Alabama.

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Retrieval

Robert H. Lokey, M.D.
Anniston, Alabama
In JAMA, 7/7/93

The small, narrow, walnut-paneled room had been used for routine ECGs before I joined the group. It was now transformed with pride (and much help from my wife) into a comfortable setting that bespoke, in my view, dignity and professional competence. Since it was still my very first week in the practice, I was not overly busy and I spent time looking about the place with satisfaction, trying to imagine how impressive it would seem to patients coming into it for the first time. Would they feel reassured (despite my newness)? Would they be intimidated by the few fine pieces Louise had provided for me (by self-denial and secret saving), like the small drop-leaf table, the leather chair?

I played out in my mind just how I would exercise the skills I had arduously acquired to put the patient at ease, then probe his or her concerns by interview and examination and, after reasoning through the data, confirm my analysis by the judicious use of laboratory investigation my residency had taught me. And then, *voila*! a satisfied and relieved patient would go forth extolling my virtues and singing my praises. Bring them on. I was ready!

Inez walked in without an appointment and no previous record with us. Her insistence had overridden the receptionist's will, and I agreed to see her (after all, I had the time). She marched into my office, pulled the leather chair around to face me, and put both elbows on my desk. (In the back of my mind I realized she hadn't noticed the room's decor at all.) She looked me square in the eye and said, "All I want to know from you is this: Do I have to die?"

Her blunt and angry question took me aback. In the rehearsals I'd mentally indulged in earlier, this scene had not played. I scrutinized her closely before I attempted a response—she was intensely jaundiced, her skin was replete with spider angiomas, a fine tremor of the hands was apparent. An alcoholic! What ironic bad luck, I silently cursed. Of all the problems our species was prey to, chronic alcohol addiction was one I felt least sympathetic toward. My only sibling had succumbed to it, and his disintegration and demise had biased me, probably irrevocably, against anyone so afflicted ever being salvaged. My residency had done nothing to amend this view. What do I do with this situation?

I began with a vague statement about the inevitability of death for us all—but she impatiently interrupted: "I'm not talking about that stuff. I mean now, soon!" As I stumbled on, through the litany of the history taking, it rapidly evolved that she had already visited another local physician, who had told her that her drinking had doomed her and she might as well go home and keep drinking. Alarm had caused her to seek another opinion. It further came out that she was the main provider for her granddaughter, and the thought of having to leave the child in the care of someone else was devastating.

This woman's anguish touched me deeply and highlighted the discomfiture I was already feeling. From previous dealings with alcoholics at this stage, I felt the earlier judgment given her was true but likely to be slowly drawn out with hell-to-pay along the way. Yet, I felt strongly moved to offer her some kind of help. The physical examination confirmed the extent of suspected liver disease.

"I must tell you there is evidence of considerable liver damage," I said to her as gently as I could make that honest conviction sound.

"Do you mean I can't get better?" she asked.

"I mean it will require an enormous effort on your part. It will not be easy, and the main hope of recovery will rest chiefly with your determination." Even as I said these things my previous experiences made me feel her chance for improvement was dim.

"Let's get at it," she replied without hesitation.

She was admitted to the hospital for careful monitoring, as the customary program for withdrawal was initiated. Within hours she became increasingly agitated and uncooperative. During the first 24 hours she

experienced some hallucinatory moments. Medication had to be given intravenously and restraints applied. During this worst time Inez fought her bonds, snarled epithets at everyone attending her, and glared unrecognizingly at me, as she showered me with curses and threats.

After this stormy time passed, and she leveled off clinically, we began to build a bridge of trust between us and she shared other dimensions of her life: a childhood of abuse and neglect. Frequent times, as an older child, she would take her younger sister in tow and find shelter in sheds and buildings for a night or two to escape the drunken rowdiness at home. She eventually resorted to alcohol herself, as a teenager. She had married a bootlegger (a revelation that did nothing for my optimism for her sustained recovery). After the accidental death of her daughter, Inez had assumed the care of her daughter's daughter. Her accounts also gave evidence that she possessed a belligerent toughness that might prove helpful, if properly directed. After a few days we discharged her and arranged for the necessary follow-ups. In those days there were not available the community-wide rehabilitation resources we have today.

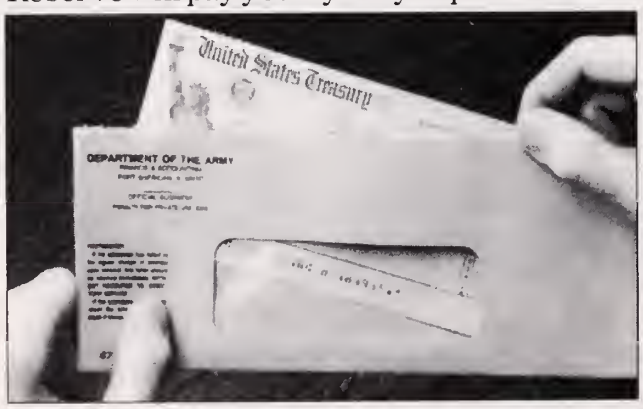
Inez never touched alcohol again. By dogged pursuit of her reclamation of self, motivated by a need to give that self for the well-being of another, Inez steadily improved. Before a year had passed her liver functions were normal and remained so; her granddaughter thrived in the loving attention provided, finished college, and continued her own journey with an example of strength and devotion as additional reservoirs to call upon, when needed.

And Inez? She died 27 years after our first meeting. of progressive coronary heart disease. The end was like the beginning—tough and determined with no self-pity.

And me? I was taught an invaluable lesson by this remarkable woman: that well-established scientific realities are certainly applicable to groups of people with shared conditions, but may fail to account for the possibilities within an individual human spirit. Inez showed me the power of sustained pursuit of the impossible.

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Disconnecting a Ventilator at the Request of a Patient Who Knows He Will Then Die: The Doctor's Anguish

*Miles J. Edwards, M.D.**
*Susan W. Tolle, M.D.**
In Annals of Internal Medicine†

Recently we assisted in withdrawing life support from a patient who had repeatedly asked to have his ventilator disconnected, even after being informed that he would then die. We found little in the medical literature to guide us, especially at the feeling level, so we are sharing our experience with the hope that others will find our emotional responses, reasoning, and procedures useful.

The Case

Mr. Larson was a 67-year-old, obese white man. At 23 years of age he developed poliomyelitis and "spent six weeks in an iron lung." His neurologic recovery was virtually complete, and he resumed a reasonably normal life.

In November 1990, he noted the onset of rapidly progressive dyspnea and weakness in his extremities. A month later, he was hospitalized. He was endotracheally intubated and then underwent a tracheostomy to provide continuous mechanical ventilation. Numerous attempts to wean the patient from the ventilator always failed within 1 to 2 minutes. He was alert and frustrated by his ventilator dependence and demonstrated some symptoms of situational depression. After careful pulmonologic and neurologic evaluation, his condition was attributed to "post-polio syndrome."

When the patient asked if he would ever be able to live without the ventilator, pulmonary and neurology consultants told him that he would always be ventilator dependent. One consultant felt that he might improve enough to be taken off the ventilator during the day but that he would probably continue to need it at night. All consultants concurred that he would never become totally ventilator independent. The patient listened and, after thinking it over, asked to have ventilatory support discontinued. He stated that he realized he would die without such support.

A psychiatrist evaluated the patient and agreed that he was somewhat depressed, although not severely enough to affect his decision-making capacity. After some initial reservations, the patient's family (one grown daughter and two grown sons) showed strong support for his decision. The patient consistently made it clear that living on continuous mechanical ventilation, with the consequent inability to speak, rendered the quality of his life unacceptable. He continued to express his wish to discontinue ventilation over a 2-week period and asked to be heavily sedated in the process. Because of his unwavering request, we were called in as ethics consultants.

Ensuring Withdrawal Is Right

We believe that after careful consideration in selected cases, withdrawal of the ventilator from an awake patient, allowing a natural death to occur, is the right thing to do. We object to the term "passive euthanasia"; it is not killing the patient. It is instead stepping aside and allowing the disease to take its natural course when that course is the consistent choice of a competent patient. The question then is whether that choice is ethically supportable in a particular patient. What do we need to consider before making this decision? And if we do decide to disconnect the ventilator, how can that be done with compassion to minimize or eliminate the patient's suffering?

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We accept the ethical and legal principles that patients have the right to refuse medical treatment, even when they may die as a result. However, we have an obligation to verify that the refusal of life-sustaining treatment is the durable request of a mentally competent, well-informed patient. In Mr. Larson's case, we needed more information before we could respond to his request. We identify seven actions that must be addressed before such a request should be acted on.

1. Clarify the prognosis.
2. Be assured of the patient's decision-making capacity (and of the absence of a medically significant depression that might temporarily affect his or her judgment).
3. Assure durability of the patient's wish.
4. Identify any coercive influences, either personal or financial.
5. Explore concurrence of all family members.
6. Explore concurrence of all members of the health care team.
7. Consider legal mandates.

During the 1 week of our consultation, we talked repeatedly to the patient, separately to all three children, and also to some close friends of the family. One son appeared to have some misgivings, but they really represented, as further inquiry revealed, his great unhappiness about his father's condition. After coming to terms with those feelings, he agreed with his father's decision. We continued to explore the attitudes of all family members. From an ethical perspective, the patient's wishes should be respected, and unanimous agreement from the family is not necessarily required. However, we did obtain unanimous agreement from the family in support of our patient's decision.

We concluded that for Mr. Larson, withdrawal of the ventilator was both legally and ethically supportable, recognizing the right of competent, informed adults to refuse medical treatment. Then came the particularly difficult question: How could this be done with compassion and with a minimum of suffering?

The Patient s Right to Sedation

Discontinuing mechanical ventilation is a uniquely difficult process for the patient, the family, the physician, and other members of the health care team. Regardless of how strongly the patient may wish to have this done. The sudden feeling of suffocation that results leads to a visceral panic. This sensation constitutes the greatest of suffering. Therefore, we believe that it is mandatory to provide sedation to awake patients before ventilation is withdrawn. Any use of sedative or narcotic analgesic medication to relieve the unwanted sensations would also reduce respiratory drive: the two are inseparable. It is a physiologic reality, then, that sedating the patient probably accelerates death by some small measure of time. However, it had been determined through multiple previous attempts to wean this patient from the ventilator that death would occur anyway, so sedating the patient would not in itself cause the death.

In Mr. Larson's case, we did not advise on the types or doses of sedatives, but we did encourage adequate sedation. We suggested that the attending physician consult with an experienced pulmonologist-intensivist on the details of ventilator withdrawal, including dosing of sedation. We acknowledge that titrating sedation is difficult when the goal is relief of suffering without deliberately inducing a respiratory arrest. Marked variability in both individual needs and drug tolerance further complicates these estimates. Ideally, the patient will be heavily sedated but will continue to maintain his or her respiratory efforts.

Our Planning

We submitted our ethics consultation report to the team and were informed by the intern that the disconnection was to be done 3 days later, on 25 February 1991 at 10:00 a.m. We suggest selecting a particular time for several reasons: It allows further time to assure durability of the patient's request, and it allows the patient and family to say final good-byes, decide who will be present, arrange last rites, and so forth; in addition, selecting a time early in the day ensures that the physician and primary nurses are available in case the patient does not die right away and needs further comfort and support. A disadvantage of setting a specific time is that any delay will be a further stress for the patient and family.

Final details were planned with the patient and the health care team. The patient requested that several members of his family be present (they wanted to be there), while others would wait in an adjoining room. The primary care team discussed who would do the disconnection and decided that the pulmonary consultant and attending staff physician would administer sedatives and disconnect the ventilator. We saw our role as ethics consultants finished.

The Disconnection

Loving family had been present throughout Mr. Larson's stay, and their numbers increased as the time

of disconnection approached. By 9 a.m., 25 February, 13 family members and close friends were at the patient's bedside awaiting the disconnection. All anticipated that this would lead to the patient's death. We were not in attendance. At 9:30 a.m., we received a call from a distraught intern telling us that the family was there and all were ready. However, both the pulmonologist and the attending physician would not be available until 5 hours later, at 3 p.m. The intern felt that she alone would have to disconnect the ventilator, something she was not technically or emotionally prepared to do and had never done before. The primary care team had not verified the pulmonary consultant's availability when the disconnection was planned. The attending physician had been called away unexpectedly and had delegated this job to the intern. We believed very strongly that this would not be an appropriate procedure for the anxious intern to do alone. Although we were both technically qualified as pulmonologist-intensivist and internist to perform the disconnection, we felt that being involved this way was beyond our role as ethics consultants. (We believe that an experienced pulmonologist-intensivist should always be involved.) Nevertheless, the patient had already waited a week while we had undertaken the seven actions outlined earlier, and we felt it would be cruel for him and his family to wait any longer. So with much trepidation, we decided that we would provide sedation and disconnect the ventilator ourselves. After this experience, we conclude that the attending physician should be the main player, with a pulmonologist-intensivist in attendance to provide necessary technical expertise. This is not a job for interns or inexperienced physicians.

We talked with the patient again to see if he still wanted this to be done and informed him that we would be performing the disconnection. He said "yes" emphatically. The family and other members of the health care team agreed. We told the patient we could not know exactly what dose of medication would be ideal and that we might err in either direction. We explained that if we judged low in our estimate, he would suffer from dyspnea. We asked his permission to reconnect the ventilator briefly if that happened, so that we could calmly administer additional medication. We would then disconnect again. He hesitated, but agreed. We again reminded him and the family that he might not die immediately. We told them that although we did not expect it, there was a slight chance he might continue to breathe for 24 hours or more. Our tests indicated he would not be able to breathe on his own, but occasionally patients live longer than we expect. If such was the case, we planned to start an intravenous drip of morphine to ensure his comfort.

A venous line was placed. We looked into the face of an alert man who we knew would soon die. Our more rational intellects told us that his disease, not us, would be the cause of his death. Deep feelings, on the other hand, were accusing us of causing death. From deep within us, feelings were speaking to us, making accusations, "You are really killing him, practicing active euthanasia, deceptively rationalizing with your intellects that there is a difference." These were not new feelings, but they were now greatly intensified as we stood there next to the patient, preparing to use syringes containing midazolam and morphine. Both are known respiratory depressants, which at high doses would be effective in active euthanasia and even at therapeutic doses would at least cause some respiratory depression and perhaps an earlier death. Nevertheless, midazolam and morphine were medically indicated to provide comfort to withdraw the ventilator in compliance with his request. We respected his right to refuse further life dependent on the ventilator. A heavy feeling of intense emotion consumed both of us as we slowly injected midazolam and morphine, watching the patient closely so we could produce the desired level of drowsiness. He reached what we thought was the correct end point, and one of us disconnected the tube to the ventilator while the other was poised at the catheter in case more medication was necessary. We stood frozen as Mr. Larson continued to take shallow but regular breaths. We felt some relief; at least we had not sedated the patient so heavily that this alone would cause his immediate death.

Within a minute or so, the patient turned slightly cyanotic and began to struggle. With trembling hands, we pushed more midazolam and morphine, reaching final total doses of 15 mg midazolam and 30 mg morphine sulfate. (These doses apply directly to this patient and are not recommended for anybody else; people differ greatly in their tolerances.) Mr. Larson seemed comfortable, breathing shallowly at a rate of 28/minute. He exchanged smiles with his daughter, who stood holding his hand across the bed. He appeared reasonably comfortable and relaxed. We both felt a great heaviness and deep sense of anxiety. To facilitate communication among the 13 friends and family, we requested further support by the patient advocate (who had also been involved throughout the earlier discussions). Several family members provided regular updates to family members in the adjoining

room. His daughter, the primary nurse, the intern, and the two of us remained at his bedside. Mr. Larson did not struggle further. About 30 minutes passed, although it seemed like hours. The patient then gradually slipped into a coma. Forty-five minutes after the disconnection, his breathing became irregular and stopped. He was not attached to any monitors, which probably reduced the strain on the family during the final minutes. His heart continued to beat for several minutes, first regularly, then with pauses. We took turns listening and waited until we were certain that he had died. Fifty-three minutes after he was disconnected from the ventilator, we pronounced him dead.

Although we received grateful hugs from the family and thanks from the health care team, we were struck by the gravity of what we had done. Doubts kept creeping into our minds. We each experienced a wave of disquieting emotion, feelings that we had killed this patient who would have otherwise continued to live connected to the ventilator. We knew intellectually that he had the legal and ethical right to refuse this medical treatment, but the gravity of his decision and our participation haunted us. We returned to our immediate commitments of caring for other patients, one of us responding next to the need of a patient who wanted medical help for a pulmonary problem to prolong his life. Both of us remained preoccupied throughout the afternoon thinking about Mr. Larson and what we had done. Our respective medical careers have generally been devoted to responding to patient wishes to postpone death and to prolong life. We've seen our patients die of their various diseases, but now our acquiescence in allowing his death caused us much anguish. This anguish continued in both of us for several days. One of us sought counsel from a psychiatrist who reinforced our belief that we did the right thing, counteracting those deep feelings that somehow we had killed this patient. Gradually we came to terms with what had happened. We had been in a complicated situation in which technology was sustaining life artificially, and we had acted on this patient's choice to refuse that treatment. Our consciences were clear, but we were left feeling very impressed with how difficult it had been to honor this man's request.

It is beyond the usual role of ethics consultants to take over patient care responsibilities and actually perform ventilator withdrawal. We do not intend to make it our practice to do this because it is really the appropriate role of the care-providers, who should enlist the help of a pulmonary-intensivist. We appreciate what we have learned from this unusual experience. After a period of reflection, we are no longer anxious about this decision, and we believe that we did the right thing in respecting Mr. Larson's request. Having witnessed from the bedside the suffering and the determination of this patient and his family, we feel better equipped to counsel other physicians whose patient care responsibilities will require them to grapple with similar end-of-life dilemmas.

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The name of our patient was changed to protect patient confidentiality, and the family granted permission to share his story.

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Mrs. William Hall
A-MASA, President

More Than Tea

A-MASA articles for 93-94 will focus on what the Auxiliary does for you -- the physicians of Alabama. Auxiliaries, working with Medical Societies across this state, send the message loud and clear that the medical community is united in our dedication to improving the health and quality of life for our communities.

The following article is provided by Emily O'Toole of Florence. She is Health Projects Chairman for the state of Alabama.

Contrary to the belief held by some, medical association auxiliary members do not meet to drink tea and socialize. Action projects that help improve the health and well being of others have long been a priority of medical association auxiliaries. A lot of effort goes into selecting and designing specific health projects that are needed within an individual community and are consistent with the goals of the medical society. Each project requires many hours of planning including: identifying resources within the auxiliary, medical society and community; establishing goals that can be reached with the resources available and within the allotted time period; evaluating the costs involved and planning various fundraising events to meed these costs; organizing and training volunteers; and publicizing the project to encourage community support.

The Jefferson County Auxiliary pooled resources to sponsor an ongoing community service project that provides a unique educational experience for children in grades K-5. BodyTrek - A Journey- Through Me is a Mobile health classroom where children learn about themselves. During an average school year, almost 8000 students will have the opportunity to visit the health classroom. Many hours are spent in planning fundraising events to finance this project. The initial cost of the project was approximately $250,000. and the annual cost to maintain the unit is $38,000.Jefferson County also sponsors an informative puppet show that goes to every elementary school and addresses the issues of handicapped children, physical abuse and sexual abuse. They also placed "Be A Winner - Shape Up For Life" coloring books in all second grade classes in the city and county schools.

Madison County placed three of the four-foot-tall soft dolls called "Organella" that are used for instruction about the human body, in three elementary schools in the city.The auxilians also participated with the "Teen Loving Children" program at Girls, Inc., by sponsoring speakers and purchasing "Luann" books for the girls, which deals with the problems of teen pregnancy and raising a baby. Tapes on the "Organ Donar Awareness" and "Teen Suicide" were made available to churches and PTAs in the county. This auxiliary raised $10,500 for various health related projects. The auxiliary is donating $25,000 toward developing a "Hands-on Science Museum" scheduled to open in 1996.

Most county auxiliaries do extensive work educating the public on the importance of mammography. Calhoun County distributed pamphlets on breast self-examination and mammography. Lauderdale County held clinics at housing projects and senior citizen apartment complexes stressing the necessity of mam-

mography. Morgan County provided free three-view mammograms to 33 indigent women and offered over 200 mammograms at half-price. Etowah County purchased mastectomy bras for local patients through the American Cancer Society.

The auxiliaries across the state continue to support many healthrelated charitable endeavors. Thousands of dollars were raised to fund scholarships that were awarded to medical and nursing students throughout the state. Programs were sponsored by the auxiliaries to educate the medical community and the public on domestic violence issues. Etowah County raised over S16,500 to distribute to 33 local charities. In addition, they purchased 10,000 teen crisis hotline cards and placed them in all junior and senior high schools.

Calhoun County Auxiliary spearheaded a program called, "Safe Taking of Pills," to educate senior citizens on the hazards of improper medicine use. The Metal Implant Bank in San Mateo, California, collects new and used orthopedic supplies and distributes them to hospitals throughout Latin America. Boxes of unused implants and orthopedic hardware, an assortment of used materials, machinery and a variety of soft goods are collected by local auxiliaries and shipped to the Metal Implant Bank for distribution. The Impairment Liaison Auxiliary Committee placed cards with a confidential helpline number for impaired physicians for family members in the doctor's lounge in every hospital in the state of Alabama.

Through its Partner-In-Education program, the Mobile County Auxiliary assisted Chickasaw Elementary School of Mathematics and Science, a magnet school for K-3rd Grade students. The auxiliary provided financial support to the school and staffed a tutor program, with volunteers from the auxiliary working one-on-one with students to improve reading, mathmatic and computer skills. Mobile County is also involved with the ongoing project Camp Rap-A-Hope, a week-long summer camp for children that have been diagnosed with cancer. The camp is free of charge to any child or teen, ages 7 - 17. The camp is staffed completely with volunteers and the auxiliary raised over $250,000 for this project. Lauderdale County Medical Auxiliary sponsored childhood immunization awareness clinics in March in honor of Doctors' Day. Much publicity was given this project by the local news media, including radio, television and newspaper interviews. In addition, a flyer was placed in every door of each housing project in the city and county to promote parent awareness.

Another fantastic continuing project is the Chrysalis Home, sponsored by the Houston County Medical Auxiliary in Dothan. This home is a haven for teenage girls who have become wards of the court through no fault of their own, but rather due to an impossibly difficult home life. Girls from ages 13 to 18 live year around with house parents in a lovely home that was constructed by the Auxiliary. The seven bedroom home has a couple who are regular house parents. Many activities are planned throughout the year to raise the money to support the home since it cost approximately $110,000 annually to maintain. What a difference the love and attention of the auxiliary and staff of the home has made in the lives of these girls.

In an age where physicians are receiving more than their share of criticism, medical association auxiliaries across the state are working very hard to show the community the extent of the physician's concern for the health care needs of the community. Other worthwhile health projects undertaken throughout the state are too numerous to mention. The auxiliaries to the medical associations of the state of Alabama continue to offer programs and projects which promote health education, identify and address health care needs and support healthrelated charitable endeavors.

Truly these dedicated and concerned individuals are making a difference and are a positive voice for the physicians of this state.

Now for a little tea and socializing!

Emily O'Toole
Health Projects Chairman A-MASA

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PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency: A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The AUC_{0-12hr} for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurum* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitounnary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticana, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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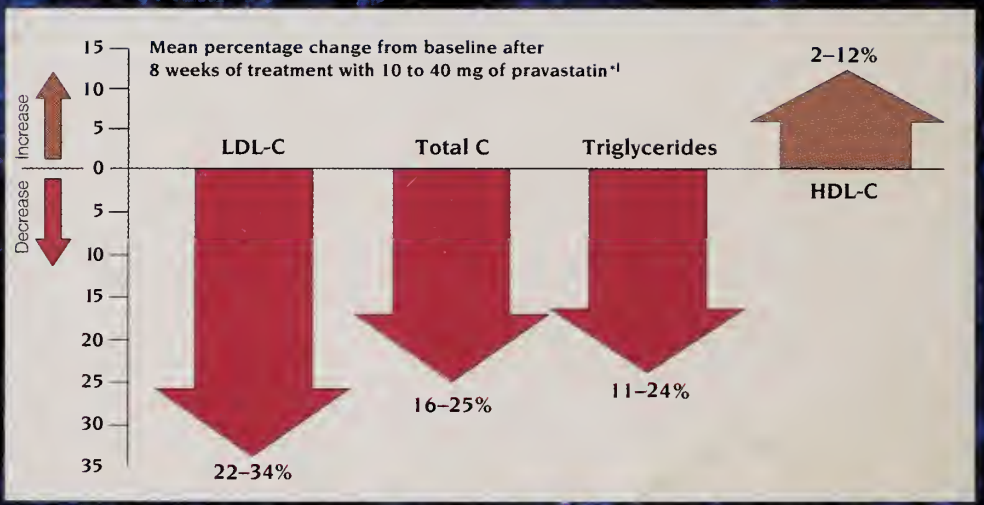
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol*. 1991;14:146-151.

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Alabama Medicine

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

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Medicine's Bum Rap

As the healthcare reform debate intensifies, reckless politicians and media opportunists are already indulging their passion for whipping boys. Physicians, predictably, are already high on the short list. MASA President James E. West, M.D., argues that this calumny ignores the uncounted millions of dollars of free care the profession has provided over the years -- receiving no recognition and asking for none.

--Pg. 4

MS

A Case in Point

A sterling example of the charity to which Dr. West refers has been the work at Birmingham's Eye Foundation Hospital, where the indigent have been treated for three decades, with doctors contributing their services and the Lions and Quarterback Clubs, along with other benefactors, providing some of the wherewithal for other costs.

--Pg. 5

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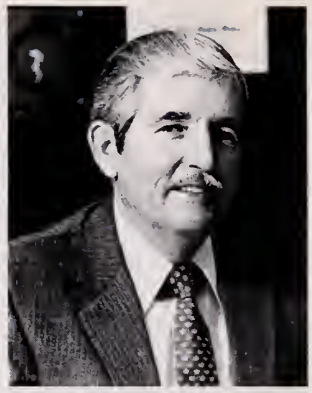
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Militant Ignorance

The fog generated on all sides in the recent budget debate does not augur well for the crucial debate on reform of the health care system, which is more complicated by a couple of orders of magnitude.

Both sides demagogued the budget issue shamelessly; and the poor public, which doesn't like or understand complicated issues anyway, was almost totally in the dark as to the merits of either case.

President Clinton called the budget, which had been greatly diluted by the time of the final vote, his "plan for recovery." Speaking for Republicans, Senate Majority Leader Bob Dole grimly predicted it would lead to recession and more unemployment.

Since not one Republican in either house voted for the Clinton budget, the President can take credit for a recovery, if it happens, as a 100% Democratic triumph. If on the other hand, Dole's prediction of another economic downturn should prove accurate, Republicans can say they were 100% right and Democrats 100% wrong.

And both would be lying, as *Newsweek* was quick to point out: the deficit reduction is supposed to come to $496 billion over five years. During that period the U.S. economy's output is expected to be $36 trillion. *Newsweek* (Aug. 16, p. 23):

"... The biggest casualty of this dreary debate, conducted with hype on both sides, has been public understanding. The whole process has perpetuated the myth that the budget serves mainly as a tool to manage the economy. Our debates are backwards. They focus on the budget's immediate economic effects and ignore the broader issue defining the scope of government — and finding ways to pay for it....

"Modest changes in government spending or taxes — and these changes are modest [compared to the size of the economy] —don't mechanically determine its behavior. Too many other things matter.... The point is not that the budget has no consequences; it is that the important consequences tend to be gradual and cumulative...."

Last year I devoted a column ("Seven Stages of Reason," *Alabama Medicine*, October 1992, p. 2) to how public opinion is formed. As a preface to a review of veteran pollster Dan Yankelovich's detailed explanation of that process, I quoted the results of a national poll sponsored by the National Council on Economic Education. The poll was designed to measure the public's understanding of the most elementary economics.

The results were dismal. But the most valuable finding was one noted by a member of the Council, William B. Walstad, director of the National Center for Research in Economic Policy, who commented:

"Many people do not understand the meaning of basic economic terms. In contrast they have very strong opinions about things about which they have no underlying knowledge."

I was interested in seeing what findings would be made about the recent budget debate inasmuch as indignant phone calls and scorching letters bombarded Washington. Well, once again the public embarrassed itself by its ignorance of virtually all of the salient facts. Surveys conducted before and after the final congressional votes revealed a public which, while eager to criticize the President and Congress, was, in the words of one poll analyst "grossly informed as to the most basic provisions of the budget deal — a public, in other words, eager to pronounce sweeping judgments on a bill with which it was com-

pletely unfamiliar."

The Wall Street Journal poll the Monday before the final vote was "striking ... and shocking." Example: 85% of people surveyed in the $20,000 to $50,000 income range bracket believed their income taxes would go up under the Clinton budget plan. Fact: income taxes would rise for working couples only if their taxable income were $140,000 or more.

The next day *USA Today* reported that its polls found that 68% believed that the bulk of the new taxes would fall on the middle class.

Gerald Seib of *The Wall Street Journal* was aghast over the mass ignorance and the outcry based on that ignorance:

"No matter what one may think of the Democrats' deficit-reduction package, it is indisputable that the overwhelming share of its taxes fall on upper income people." Still, people refused to believe it.

Time magazine was similarly perplexed:

"Republican lawmakers and conservative talk-show hosts had succeeded in frightening many Americans into the mistaken belief that the middle class will bear the brunt of Clinton's new taxes."

This outrageous public ignorance is not, unhappily, a new phenomenon. It is in fact the major reason for the mess in Washington: the electorate is so poorly informed on all major issues that there is no sure inhibition to lawmakers saying just about anything they want to. Thanks to public apathy, they are not required to be well informed themselves.

Americans, according to many surveys over the years, are the most poorly informed on public issues of any population in the industrialized western nations. And, at the same time, the most opinionated.

By contrast to the complexities of the coming health care reform debate, the budget brawl was kindergarten stuff. We have undertaken to re-invent one-seventh of the U.S. economy. During that debate, you will hear many pandering orators of both parties praising the "wisdom of the American people."

Prediction: if it becomes a fog-generating contest between demagogues on both sides, each group cynically exploiting the public's ignorance and indifference to the facts, whatever results will be a national disaster.

I hope I am wrong, but I seriously question whether a rational formula can ever be found in such an environment of myth, misinformation, rumor and downright fabrication.



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PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

Medicine's Eternal Bum Rap

The bum rap physicians have received over recent years, and the calumny that will almost certainly be added in the debate over healthcare system reform, is the product of many factors — envy being only one of them.

Down through the ages of our profession the esteem in which we have been held by our patients has always been galling to outsiders, as of course is our relatively high income. No allowance is made by our critics for the years we spent in training, the heavy responsibilities we bear, the long days and nights of toil, the occupational hazard of never being able really to escape from our duties, the stresses on our families, and all the rest.

The "opportunity cost" of medical practice is very high, to use that curious phrase of economists describing what we sacrifice to serve as physicians. Were it not for the "psychic income" of medicine, another technocratic phrase, the immense intangible rewards of serving mankind, how many of us would work as hard as we do and suffer the deprivations of free time others enjoy?

Our reckless critics, alas, persist in defaming us as interested only in luxury homes and cars, endless golf and counting our gold bullion. Maybe if we had had an anti-defamation league of some sort over the years, we could have more effectively debunked the insulting myths, but I doubt it. A wise Greek before the time of Christ said it for the ages: "People believe what they want to believe."

Professional reticence compels us to hide our lights under a bushel, thus disabling us from answering the frequently heard canard that doctors don't do good works anymore. On the facing page is a sterling example of the falsity of this charge.

Alabama physicians routinely donate millions of dollars a year in free care that the general public knows little if anything about. People don't know because we don't shout it from the rooftops. Medicine has been properly labeled "The Quiet Art." I hope it will always remain so, but in an age when even many ministers take to the television tube to proclaim their greatness, when our people idolize obstreperous rock musicians and assorted other raucous, ill-mannered and downright amoral "celebrities" as national heroes, the immemorial modesty of medicine scarcely stands a chance of recognition.

Since I would not change that modesty, I doubt there is an effective defense to the lies of unscrupulous politicians and the legions of ignorant and/or malicious commentators in the media. Let a bad apple in the profession make the news for some outrageous sin of omission or commission and the sordid details are trumpeted to the heavens — while thousands of other physicians are quietly pursuing their art, unhonored and unsung even when the care they provide is uncompensated.

Without any real hope that it will be noted, following is a brief summary of the free care provided by American and Alabama physicians. Three years ago, in the fall of 1990, the AMA's Socioeconomic Monitoring System conducted a careful, in-depth study of the charity care provided by doctors national-

continued on page 33

Free Eye Care From the Eye Foundation Hospital in Birmingham, Alabama

Alston Callahan, M.D.

Doctor Callahan

Alston Callahan, M.D., F.A.C.S., F.R.S.M., a Mississippi native, graduated from Tulane Medical School in 1933. With his wife and children, he moved to Birmingham after World War II and was befriended by the families of Robert Ingalls Sr., John E. Meyer, James A. Simpson, Frank E. Spain, Thomas E. Bradford, and Craig Smith, who became his patients. With their help he became the physician-founder of the Eye Foundation Hospital, which opened for patients in 1964. He was joined later by other leaders, including Hall Thompson, Carl Jernigan, John M. Harbert III, Wallace Malone, and then sons of the early trustees. A clinic building was constructed to serve the needs of Alabama's indigent eye population. As this article explains, about a fourth of the service rendered is for poor patients, three-fourths for private patients.

In 1972, the Eye Foundation trustees agreed to combine their resident training program and research efforts with the UAB Medical School. Now, 165 ophthalmologists have received their training at this institution, and besides the M.D.s involved in research, six Ph.D.s are working in the Angelo Bruno Eye Research Laboratory at the Eye Foundation to discover more of the functions and malfunctions of the retina.

A recognized author of many ophthalmic books and articles, Dr. Callahan, at 79, turned over his practice to his son, Michael, and became a full-time, volunteer fund raiser for the charitable and retinal research work at the Eye Foundation Hospital. His two previous articles for Alabama Medicine were "The UAB Medical Deans: their Impact on Alabama Medicine with Personal Remembrances" (December 1991), and "The UAB School of Medicine. The Founders and the Almost Forgotten Essential Doctor: Harry Lee Jackson" (December 1992). During this year, he has traveled to Tombouctou in West Africa, and to the North Pole on a Soviet icebreaker.

— William H. McDonald

The Eye Foundation began serving the people of Alabama and of the Southeastern United States in 1964, before President Lyndon Johnson and the U.S. Congress instituted Medicare and Medicaid (Fig. 1). At the outset, a free eye clinic was organized by the Eye Foundation ophthalmologists for patients referred by the Alabama Lions Sight Conservation Association and the Lions Clubs of Alabama. The original partnership-agreement between the ophthalmologists and ALSCA was that the eye surgeons would make the eye examinations, prescribe the treatment, and perform the surgery all without charge, and that ALSCA would provide the cost of hospitalizations, medicines, and glasses.

In 1965, a program for training residents was established at the Eye Foundation, and approved by the Council of Graduate Medical Education of the AMA, the American Hospital Association, and the American Academy of Ophthalmology. This not only trained young physicians to become ophthalmologists, but with their help, the increasing number of indigent eye patients could be helped. In the same year, Medicare was implemented, paying for some hospitalization costs for these patients, which lightened the financial strain on ALSCA, and payments were also directed toward the eye surgeons. These fees were less than half the usual private patient fees, but, nevertheless, money was allocated to the surgeons.

At this point in medical history, all of the ophthalmic surgeons at the Eye Foundation Hospital agreed to donate these fees they received from indi-



Fig. 1



Fig. 2

gent patient treatment and surgery to the hospital building fund. This demonstrated to other generous donors and foundations that our doctors themselves wanted to contribute toward better equipment and facilities. This fund, designated as the "Physicians Donated Capital," from 1966 to 1971 amounted to about $2 million. When Medicaid was instituted later, additional, though smaller, amounts of money for those patients were added in payment for hospital expenses and to the surgeons. These funds were also given to the Physicians Donated Capital. With additional funds from the Ingalls Foundation, the Meyer Foundation, and later the Greater Birmingham Foundation, the hospital was expanded, adding another floor and constructing the Ellen Gregg Ingalls Eye Research Institute. In addition, two of the staff ophthalmologists gave from personal funds more than half a million dollars each for the further development of the hospital. As more indigent patients applied for help, in 1975 an outpatient clinic building was constructed to serve them.

In 1971, the University of Alabama in Birmingham asked the trustees of the Eye Foundation if the UAB residency in ophthalmology could be combined with the residency program of the Eye Foundation, and if the offices of the Department of Ophthalmology could be located in the Eye Foundation Hospital. Because this would mean that the ophthalmologists could be better trained and more patients helped, the Eye Foundation trustees agreed. Most, though not all, of the ophthalmologists accepted appointments to the voluntary UAB faculty. This meant that they would teach without financial payment. Also at this time, a full-time (salaried) staff was begun with the selection of the department chairman.

It soon became apparent that the cost of operating UAB's Department of Ophthalmology (rent, telephones, utilities, secretaries' salaries, technicians' salaries, etc.) would exceed considerably UAB's ability to provide the necessary funds. Then, the department chairman asked the physicians at the Eye Foundation Hospital and the Eye Foundation trustees to shift the direction of the PDC from construction and equipment for the Eye Hospital toward the costs of the Department of Ophthalmology. After reflection and consideration, this request was approved, and thus these funds generated by the voluntary faculty members were used to help the department activities, including equipment for the indigent clinic.

During the next 20 years, 1971-1991, these fees amounted to $1,535,112. In the fiscal year 1992-93 alone, the "physicians' donated capital" amounted to $95,329.28. However, these fees from the PDC do not even begin to make up the necessary financing for the Department of Ophthalmology. The funding necessary for the department comes from the professional services provided to the patients by the full-time faculty (Chairman Dr. Harold Skalka and eight others). The 1992-93 budget for the UAB's Department of Ophthalmology is more than $2.5 million, including research activities, to which UAB's direct contribution is about $225,000. It should be noted that included in the cost of the Department of Ophthalmology are the salaries of the full-time ophthalmologists, most or all of whom produce more funds than they receive. (This is typical throughout the clinical departments of UAB.)

The Eye Foundation Eye Emergency Room

The emergency unit at the Eye Foundation Hospital is open and available every minute of the day and night, serving patients from all over Alabama and the Southeast. It's the only fully staffed eye emergency room in the state, with one or more of our 18 resident ophthalmologists always on duty. Others are available when and if needed. For serious eye injuries in which the fate of the eye and vision must be decided, a senior attending staff member assists in consultation. Ophthalmic subspecialists in pediatric ophthalmology, retina and vitreous, neuro-ophthalmology, cornea and orbital adnexa are always available.

Ambulatory patients with eye injuries who apply to other emergency rooms at other hospitals in the UAB complex are referred to the Eye Foundation emergency unit. When the patient is not ambulatory, as for example because of severe body burns, and is in an intensive care unit, a resident ophthalmologist will evaluate the eye problem in that unit, and other residents will "staff" the Eye Foundation emergency room.

More than 7,000 private and indigent patients are examined and treated annually in the EFH emergency unit. Weekends are the busiest, and on some holidays, as July 4th, as many as a dozen patients will apply for help within a few hours. Of the patients we see and



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examine, about 15% or more are without funds. None are turned away. Although the majority are self-paying or patients with insurance, the cost of supplies and staff for the indigent make a financial break-even difficult. For elderly patients at the poverty level, there is a fund available for the emergency room costs, donated by Mrs. Leanore Aland in honor of her late husband, Leon.

The Alabama Lions Sight Conservation Association

For nearly 50 years, ALSCA has been a steadfast angel in aiding indigent Alabama patients who have eye diseases, injuries, and who need glasses. Organized in 1945 by the 225 Lions Clubs of Alabama, it has functioned continually and has been of increasing service for over half of a century. Its home office is in Birmingham at the Eye Foundation Hospital. The trustees of the Eye Foundation, Inc. subsidize the office, waiting room, and examining rooms for nearly 4,000 square feet of space, and provide diagnostic and minor treatment facilities for indigent patients at an annual cost of nearly $300,000. ALSCA is a statewide organization with offices in Montgomery and Mobile, and it is supported by the 225 Lions Clubs throughout Alabama, and certain foundations, corporations, and individuals.

ALSCA acts as both a collecting service for applicants throughout Alabama, and a screening service to verify that its patients are without sufficient funds to pay for ophthalmic care. It furnishes the patients for the clinic in Birmingham, and for individual doctors who treat its patients without charge throughout the state.

Benefits for Indigent Patients from the Joint Efforts of the Eye Foundation Trustees, Physicians, and the Alabama Lions Sight Conservation Association—

The Alabama Lions Sight Eye Clinic

The Alabama Lions Sight Clinic is located in the Lions Eye Clinic building, a part of the Eye Foundation Hospital complex. It is staffed with one senior ophthalmologist with five residents from the group of 18, with consultants available for all ophthalmic subspecialties, including pediatric ophthalmology, retinal and vitreous surgery, neuroophthalmology, orbital and reconstructive and plastic surgery. The clinic is held every day from 8:30 until 4:00. Twenty to 30 indigent patients are examined each day; for the fiscal year ending June 30,1993, there were 7,509 examinations made and treatments given (Fig. 2.)

Free Surgery at the Eye Foundation Hospital

Nearly 600 eye operations are performed at the Eye Foundation Hospital each year without charge, which would cost private patients somewhere in the neighborhood of a million dollars for this surgical care. These operations are for cataract extraction, straightening of crossed eyes, repair of injured eyes, removal of benign and malignant tumors of the eye and eyelids, corrections of malfunctions of the tear sacs, for dry eye syndrome, reattachment of dislocated retinas, corneal transplants (grafts), removal of blind painful eyes, and reconstructive procedures as socket enlargement, malfunctions of the eyelids and tear sacs, etc.

These procedures are performed by the resident ophthalmologists with the help of the senior ophthalmic surgeons who receive no financial recompense. There are some fees paid for some of these patients by Medicare, and a few by Medicaid. However, as mentioned above, these professional fees are turned over to the Department of Ophthalmology and UAB for its myriad of functions.

In the early 70s, Alabama Lions Sight was able to pay the actual hospital costs for surgery, but as the daily hospital rate increased from $150 a day to more than $1500 a day, they, the Lions Clubs, could not keep up with the increased costs. The Quarterback Club appropriates between $75,000 and $100,000 every January, to pay for sutures, surgical drugs, and part of the nurses' salaries, but even so, by June or July all funds are expended.

For the fiscal year 1992-93, there was a total of private and charity patients operated upon of 3,495, more than one-fifth without charge.

Free Spectacle Glasses

A frequent and recurring statement of applicants to ALSCA is that "My child can't see good." If the parent's income is sufficiently low to qualify for ALSCA clinic admission, the child is given an appointment, and the refraction (examination for glasses) is performed by one of the residents with a senior admitting staff ophthalmologist available for complex cases. Most, but not all, of those referred do need glasses to correct nearsightedness, farsightedness, or astigmatism. Each month of the year about 100 pairs of spectacle glasses of the proper strength in a strong simple frame are given to the children and adults who need them, without charge.

For cataract patients, a wonderful improvement has occurred in the last few years. Instead of having to wear thick, unsightly spectacle glasses after surgery, as has been true in the past, corrective plastic lenses

Discover The Elegance Of A Hybrid



At first glance, it's the ***beauty*** of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its ***elegance*** becomes apparent—a gentle blend of softness and strength.

At first glance, it's the ***enhanced performance*** of Vaseretic that catches the eye. But study Vaseretic more closely, and its ***elegance*** becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid ***blending of tolerability and power*** that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

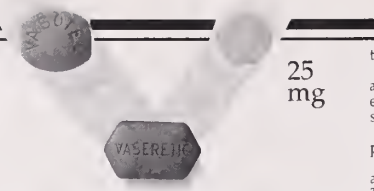
Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*



CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General: Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy; Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC® should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5. 6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate; Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent pre-existing renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium, this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions; Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide; When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Cholestyramine and colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively. Thiazides may be administered two to four hours before the resin when the two drugs are used concomitantly.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

* Registered trademark of Hospal Ltd.

one marrow assay.

nalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril as also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, espectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test vith or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: ec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, nd the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 o 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of ydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and emale rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*.

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole*: Syncope, chest pain, abdominal pain; *Cardiovascular*: Orthostatic hypotension, palpitation, tachycardia; *Digestive*: Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric*: Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin*: Pruritus, rash; *Other*: Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough*.

Clinical Laboratory Test Findings, Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole*: Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular*: Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia; atrial fibrillation; hypotension; angina pectoris; *Digestive*: Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic*: Rare cases of neutropenia, thrombocytopenia and bone marrow depression, a few cases of hemolysis in patients with G-6-PD deficiency have been reported in which a causal relationship to enalapril cannot be excluded; *Nervous System/Psychiatric*: Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital*: Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory*: Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin*: Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, alopecia, flushing, photosensitivity; *Special Senses*: Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*.

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive*: Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic*: Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity*: Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal*: Muscle spasm; *Nervous System/Psychiatric*: Restlessness; *Renal*: Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin*: Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses*: Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

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are now implanted within the eye. With this aid, the patient sees well at a distance without glasses, and needs them only for reading.

The monthly cost of the glasses supplied by ALSCA is about $3,000, or $36,000 a year. These are paid for by donations to ALSCA by the Alabama Lions Clubs, by donations from foundations and funds (such as the Julia P. Wittichen Fund), and individuals, among whom are Mr. and Mrs. R. C. Cobb.

Free Medications

The prescriptions written by the ophthalmology residents and physicians at the Eye Foundation Hospital are paid for by Alabama Lions Sight, at a cost of about $3,500 a month.

In addition, many pharmaceutical companies give a large supply of their products to be used by the charity patients. The prescriptions are for the treatment of eye infections and other eye diseases, especially for chronic glaucoma. This condition is a lifetime health problem for the patient, and his/her physician and the clinic clerical staff. At regular intervals, sometimes monthly, and sometimes more or less frequently, glaucoma patients must attend the eye clinic for their eye pressures to be measured and recorded, and for many patients to have their peripheral field charted to be sure that peripheral vision is not being lost. The eye pressure must be kept down within normal limits; if it rises above 20 mm Hg, the peripheral field will gradually be eroded away until the central fields are reached and destroyed, and the patient is then blinded. Glaucoma patients must instill anti-glaucoma drops in their eyes several times a day, and some must take oral medication to suppress the formation of aqueous fluid within the eye.

Alabama Eye and Tissue Bank Human Eyes Furnished Free

Six hundred and seventy-four eyes were carefully examined, approved, and furnished without charge by this organization for corneal transplantation (grafts) and research and teaching in the fiscal year ending June 1993, more than one-fourth of the total number of eyes (2,466) obtained during this time. The gift of these 674 eyes represents a donation of $346 ,730 .

The headquarters of the Alabama Eye and Tissue Bank is in the Eye Foundation Hospital, and it maintains offices also in Mobile, Huntsville, and Montgomery, obtaining and furnishing eyes throughout Alabama through this network. The Alabama Eye and Tissue Bank is governed by an independent board of trustees. It is a charter member of the Eye Bank Association of America, and the Pan American Association of Eye Banks.

During its first year of 1970, it obtained only six eyes for corneal transplant. After nine years of slow growth, only 186 eyes were obtained. However, with a new executive director, new staff, and renewed enthusiasm from its board of trustees, it began to grow almost exponentially, reaching in the last fiscal year, 2,466, making it the seventh largest in the United States of America.

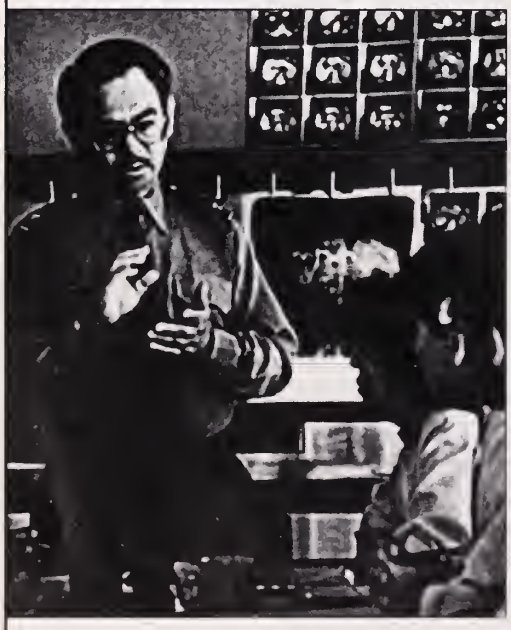
Income to the Alabama Eye and Tissue Bank is furnished by donations from individuals, foundations, and corporations, as well as special promotions, such as the sale of photographs of sports figures, etc. The largest source of income is payment by third-party reimbursement for processing of the eyes. The donors' families are not paid for the eyes, nor do the recipients pay. But the scientific process of insuring that the tissues are free from AIDS and other communicable diseases, and that the tissues, especially the corneal endothelium, are healthy, requires laboratory studies and technical skills. The Bank certifies that the cornea to be used has every chance of remaining crystal clear and giving the recipient good vision. Though the greater number of corneal transplant operations are performed in Birmingham, a significant number of these operations is performed in Mobile, Huntsville, and Montgomery.

THE PROBLEM

The Eye Foundation Hospital is a facility in which each year more than a million dollars worth of "free eye surgery" is performed. With the cooperation of the Alabama Lions Sight Conservation Association, the Birmingham Quarterback Club, and the assistance of many philanthropic organizations and foundations, at least a millions dollars in funds for tangibles as intraocular lenses, medicines, spectacle glasses are furnished each year to patients who have no medical insurance and little or no income. These are a few examples of the generosity of the medical profession and supporting institutions in the United States that for decades have helped those who are unable to help themselves, or who need to have this help in order to later become employed or self-supporting.

Now, the problem is how can services be given to these patients otherwise? Will the Clinton proposals dismantle this structure so carefully evolved over several decades? Are taxes to be raised high enough to pay for this? The surgery fees that are being paid to the surgeons are being greatly reduced. Can doctors continue to perform free surgery? And will the individuals in the organizations that are so generous in making it possible for patients to have free surgery, free intraocular lenses, etc. still be able to continue this?

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Diabetes and Vision

Bernard H. Eichold II, M.D., Dr.P.H.
Saunders Lee Hupp, M.D.

Many of us are involved in the treatment of diabetes; and yet only half of the 250,000 people in Alabama with diabetes have any idea that they have this disease. Recent statistics indicate it is now the seventh leading cause of death in Alabama, higher than the national average. As we know, diabetic morbidity has such an impact on our patients health because of multi-system complications. But the link between vision and diabetes often is not the primary focus of a treatment plan.

Results of a seven-year-long collaboration in Mobile indicate the benefits of placing greater emphasis on the visual function of diabetic patients. In 1986, CDC awarded a small grant to a joint effort aimed toward controlling and preventing diabetes and its associated complications to the Mobile County Health Department. The University of South Alabama Department of Ophthalmology and the Family Oriented Primary Care Clinic (located at the Mobile County Health Department) formed a collaborative partnership to screen and treat indigent diabetic patients. Through this community approach over 2,000 diabetics have been provided comprehensive medical care.

The primary medical needs of the indigent diabetic patients enrolled in this program are provided by the Family Oriented Primary Care Clinic. The Health Officer of Mobile County, Dr. Bernard Eichold, serves as the Medical Director of this program and provides primary care most needed by the people enrolled in the program. Complete physicals and lab workups, complication education, and nutrition assessment are a routine part of controlling their diabetes. The Mobile County Health Department funds most of the cost of this care since it is not covered by the grant.

Initially, the Diabetes Control Project staff in Mobile developed protocols which targeted diabetic complications for extensive analysis and follow-up. It is recognized that diabetes is the leading cause of blindness in Americans in their productive years. Diabetes may adversely affect visual function by a number of mechanisms. Patients with diabetes have an increased incidence of glaucoma, cataracts, and even more significantly are prone to blood vessel damage from diabetic retinopathy.

Diabetic retinopathy affects vision in diabetes by two main mechanisms. First, the already existing retinal blood vessel structure becomes leaky and diabetic patients develop hemorrhages, exudates, and macular edema. Macular edema is a swelling or fluid accumulation in the retina causing visual distortion. Second, abnormal or proliferative blood vessels may develop over the retina of a patient with diabetes and, subsequently, bleed. Once bleeding has occurred over the retina and in the vitreous cavity, permanent scarring and severe visual loss are not uncommon. The likelihood a patient will develop diabetic retinopathy increases the longer they have diabetes. Those patients that have had diabetes for 15 years or longer have about an 80% chance of developing either background or proliferative retinopathy. Proliferative diabetic retinopathy, the most threatening form of retinopathy, is present in 25% of Type 1 diabetics and often remains asymptomatic well beyond the optimal stage of treatment.

New technology, however, allows for successful treatment of these complications. Two important large clinical trials, The Early Treatment Diabetic Retinopathy Study and The Diabetic Retinopathy Study, have demonstrated that laser surgery can reduce the risk of visual loss from both proliferative retinopathy and macular edema by at least 50%. Even greater reduction in vision loss can be expected if the retinopathy is discovered at its earliest stages. It was also found that vitrectomy surgery can restore useful vision to some people whose retinopathy is too advanced for laser surgery.

The National Institute of Health began a prospective multi-site trial study 10 years ago to determine if diabetic complications could be slowed or prevented through better control of blood glucose levels. The

DCCT (Diabetes Control and Complications Trial) results are out and has shown that diabetes complications can be slowed or prevented through better control of blood glucose levels. The American Diabetes Association has issued a position statement on the implications of the DCCT in which they convey some of the preliminary findings. They state "there was an approximate 60% reduction in risk between the intensive treatment group and the standard treatment group in diabetic retinopathy, nephropathy and neuropathy. The benefit of intensive therapy resulted in a delay in the onset and a major slowing of the progression of these three complications."

Because recognizing that visual loss is quite probable and may be prevented by early treatment in the diabetic population, the Mobile County Health Department collaborated with the Department of Ophthalmology at The University of South Alabama and the local ophthalmologic community to treat and follow the indigent population of south Alabama. Over the past several years a close working relationship has developed and it is a good example of how limited resources can be directed toward a common goal to achieve beneficial results for the community.

Having completed a dilated eye examination within the past year is a key goal of this community program. For those confirmed diabetic patients who have not had an eye exam in the last year, a complete dilated exam is provided through referral to the University of South Alabama Department of Ophthalmology.

This diabetic eye assessment program is headed by Dr. Saunders Hupp. The results of the first year of operation of the clinic at the Mobile County Health Department found 255 adult indigent patients who were diabetic. Ocular complications were found in 132 patients with 22% requiring treatment. Biomicroscopy, color photography and fluorescein angiography were used to identify and classify the ocular pathology. Approximately 29% of the patients were found to have background diabetic retinopathy, with an average duration of 13 years. Of these, 13% also had clinical macular edema. Proliferative diabetic retinopathy occurred in 2.3% of the Health Department patients. The presence of diabetic retinopathy correlated with duration of disease, but not with sex, race, or hypertension. About 5% had glaucoma, and 6% had visually significant cataracts. Unfortunately, another noteworthy finding of the study was that black males do not seek care and, therefore, are more at risk for diabetic related morbidity and mortality.

Since that time, enrollment has grown and over 200 new diabetics are expected to enroll at the Mobile County Health Department this year, with over 300 eye exams being performed at the University of South Alabama and by other ophthalmologists in the community. For the last year in which aggregate statistics are available, 38% of the referred patients were found to have background retinopathy, 28% had cataracts, 15% had suspect of glaucoma, 9% maculopathy, 6% proliferative retinopathy, 2% glaucoma and 2% hypertensive retinopathy. It is estimated that this program has prevented blindness in over 60 people, and it has prevented over ninety people from suffering with retinopathy. It certainly can be stated that the vision of diabetics in south Alabama has improved because of awareness of the need for identifying possible loss of visual acuity on a regular basis. The same should hold true for any similar population group.

Since its beginning in 1987 with the development of the Diabetes Control Project in Mobile, this project has spread over the State of Alabama. Currently, Birmingham, Montgomery, and Dothan have Diabetes Control Projects along with Mobile. With



"Ron's Rule—I give myself one week to meet new people and start having fun on a locum tenens assignment. It hasn't failed me yet."

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the development of this statewide project, a Diabetes Advisory Council has also been created to oversee the functioning of these individual projects as well as to serve as a statewide information center on all aspects of diabetic care. The Council's Executive Director is Mr. Braxton Moore, the State Diabetes Project Manager, located at the State Department of Health in Montgomery. Both Drs. Eichold and Hupp have been active on the Advisory Council for the last several years.

Recently, the American Academy of Ophthalmology launched a program called Diabetes 2000 directed at eliminating preventable blindness by the year 2000, which correlates strongly with the DCCT results. Too many people with diabetes are progressing to the point of irreversible vision loss by the time they are seen by a physician or ophthalmologist. Therefore, the American Academy of Ophthalmology has developed a program to assist primary care physicians with timely recognition of early signs of diabetic eye disease so that prudent referrals can be made.

Diabetes 2000 is a long-term education program aimed at reducing ocular complications of diabetic patients. Since there is usually a lengthy time lag between new clinically relevant discoveries and their use in direct patient care, this effort hopes to reduce this wait by communicating new data directly to physicians through educational programs and seminars throughout the county. In later stages of Diabetes 2000 there will also be educational programs for diabetic patients.

Remember when reviewing your diabetic patients profile the factors affecting this particular complication are:

1. Duration of the disease
2. Hypertension
3. Hemoglobin A_1c

Diabetes 2000 recommendations based on the American Academy of Ophthalmology's Diabetic Retinopathy Preferred Practice Patterns include:

1. Any newly diagnosed adult diabetic needs a dilated eye exam now

2. Previously diagnosed adult diabetic should receive a dilated eye exam once a year

3. Juvenile diabetics should receive a dilated eye exam within five years of onset

The program here in south Alabama has implemented the guidelines recommended by Diabetes 2000 successfully, and we will closely monitor the findings of the DCCT for further refinements to our program. The project continues to grow in Mobile, although the financial support does not, we strongly believe in its long term costs benefits. This is one example of how a community can address the complications of diabetes and thereby reduce the impact of one of our leading causes of death.

Emphasis on a patients visual function throughout the disease process can produce significant quality of life benefits for diabetic patients.

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Drug Abuse: The Secret Family Illness

Gerald L. Summer, M.D.
Physicians Recovery Network

The following letter emphasizes the family's distress in chemical dependency and discusses common emotional reactions to alcohol and drug problems. Assuming responsibility for the drug/alcohol dependent family members illness is the usual scenario. Stages of progression of the family illness is primarily a result of denial. In a strong denial system, family members can be deluded into not recognizing any existing problems. Common disorders include sexual problems, headaches, anxiety, depression, eating disorders, insomnia, and juvenile delinquency. Family members themselves withdraw from social participation because of the fear of visibility of unacceptable behavior. The spouse finds methods to deal with mounting anxiety and frustration, and generally speaking, the methods devised are not conducive to helping the addicted family member recognize his/her problem. Retreating into silence, the spouse develops somatic symptoms, depression, high anxiety levels, and even violence. The spouse may ultimately find ways to separate and protect herself/himself from the continued infliction of emotional pain.

Through education and recognition, recovery is possible for every family member. He/she can again become a healthy, functioning person again. The spiritual and emotional havoc created by alcoholism/addiction has a solution. The solution is clearly presented in the following letter from an Alabama physician's spouse who desires to remain anonymous.

An Open Letter to Spouses of a Chemically Dependent Professional

"Because of the joy and peace of mind that I have received in a program of recovery from the Disease or Addiction (Chemical Dependency), I want to share a little bit of my life with any spouse that might be experiencing some of the same things I had in my life for over 25 years. Since denial is the primary symptom in the addict's family, as well as the addict, I hope if you have read this far, that you will continue and reflect upon your own life. You may be able to find peace in the same way I did.

"If you had told me about five years ago that I was a controlling, dominating, angry, inconsiderate, incompetent person, I would have said you were totally wrong. After all, I was the one who was under the influence of alcohol or some other drug. I was the one who kept the practice (business) going. I was the one who kept the patients satisfied when he was not able to talk with them on the phone. I was the one who did all the ordering, paying of the bills, putting out the little fires in the office and at home. I was the one who saw to it that the children were bathed, fed, dressed, to school on time, to ball practice on time, to church on time, had their lessons, had presents under the tree at Christmas, etc.

"I was the one that was doing what was right, and you could in no way tell me that I was inconsiderate of others! I was the sober one in my family, and I was the one who had to keep this secret from everyone around us. I covered for and covered up for many years — thinking all the time that I was doing what was right. I was the protector of my family, and I was responsible for everything that happened to them. My life was a reaction to those around me, and rarely did I act on my own. Because I had been put down for so long, I did not feel capable of taking action on my own. I looked to others to see how I felt. If you felt okay, I felt okay. If you were upset, I was upset. If you were angry, I was angry.

"Just a few weeks before he hit his bottom, as they say, I realize now that I hit mine. I truly was so devastated that I didn't care about anything — my family, my work, my life. I had never before reached the point of not caring. I even felt guilty because I didn't care. I had been taught to care about people, to do good for people, to respect people. Now I was in such a poor mental, physical, emotional, and spiritual state that I did not care whether I lived or died. My life as I knew it was a total wreck. I didn't even have enough strength to leave my husband. I didn't want to stay, and I didn't want to go. I was a total failure at everything I held dear to me.

"After my husband was admitted to a treatment center that dealt with a lot of medical professionals, I attended a family week where the 'light bulb' in my

mind was turned on to reality and truth. My husband had a DISEASE, much like diabetes and cancer. It is a horrible, incurable, cunning, baffling, probably hereditary, and FATAL DISEASE. He could not help it, he did not ask for it or want it, but he had it — and it had him. He was totally incapable of doing anything about his problem at this time. He wanted to quit, but he couldn't. He wanted to control his drinking and be like other people around him, but he could not. He was dying. He was not a bad person, a sorry human being, a poor father and husband. He was a sick person who by now realized he needed help. Many good years had been wasted because of this disease, and a lot of damage was done to our family, especially our two sons. Thank God, some of the scars are slowly being healed.

"From the wonderful sharing that I heard form others during the time my husband was in treatment, I have learned that there is a solution to our problem. I say 'our' problem because alcoholism is a family illness. It affects everyone in the family and those close to the alcoholic. It is totally false when one says, 'I'm only hurting myself.' I could identify with the wives who felt angry and guilty and ashamed. I had the same thoughts as others. I had spent lonely hours waiting for him to come home, then being so angry when he arrived that all I could do was scream and fuss. I criticized him when he didn't work around the house, but made excuses for him when the neighbors noticed that the yard was not cut. I had dreamed of the time when I would get a call in the night that he had been killed in a horrible truck accident. (I diligently kept the life insurance paid). I pictured the funeral with all the patients and friends paying their respects to our family. I actually experienced the relief that I would have when he was no longer around to cause us trouble. Then, the very next minute, I would be full of guilt and could not believe that I had ever thought such a thing! Total insanity... But, I learned that I was not alone with these crazy thoughts. Some wives had worse dreams than I had. I wasn't really crazy, I was caught up in the roller coaster of alcoholism. I didn't even drink. I didn't have a problem with the alcohol, but I surely had the 'ism.' I needed help just as much as he did.

"While at the family week, I was told that I didn't cause his illness, I couldn't control it, and I certainly couldn't cure it. What a relief! I had felt responsible for so long, and I was being told this was HIS disease, but it had affected me. He is responsible for HIS recovery, and I am responsible for MY recovery. The pressure was relieved, and I could begin my journey of recovery, but I had to allow him the dignity to begin his. I found a new way of life that is wonderful. Although I have always been active in church, I have found that I can let go of others and let God take care of them. After all, HE is the only one that can take care of us. He has and continues to do for us what we could not and cannot do for ourselves. I continue to be amazed at the peace it gives to be able to get out of the driver seat through life. I try now to do the peddling and let God do the steering.

"My point here is not to tell you how bad my life was, but to tell anyone who might be living like that, *There is hope. There is a solution to the problems caused by Alcoholism/Addiction.*

"I want to encourage you to go to ALANON meetings. This support group is for ME and for YOU. The program that is available has saved my life. You don't have to be concerned that someone might know you or tell others that you came to a meeting. Your anonymity is respected. You don't have to give your name or even speak, just listen. Everything said is confidential.

"Space does not permit me to share all I would like to share with you. I can only share MY experience, strength and hope. I have found that I only receive form this program of recovery when I am willing to give to others who are still suffering. I get what I give, and I can't afford not to give to others, because I want everything I can possibly get out of the rest of my life.

"We are blessed in our state to have a Physicians Recovery Network that believes the family of the alcoholic or addict needs as much help as the addict. There are spouses groups in several cities in our state, and Dr. Gerald Summer, who directs the state program, can put you in touch with someone near you. I have given him my name and phone number, and there are others who are willing to share also. It is my hope and prayer that if you or someone you love has a problem with alcohol or drugs, you will call the Montgomery helpline and get your blessing. You have my permission to call me if there is anything I can do to help you understand how you might have been affected.

"There is no need for shame and embarrassment. Let's get out of the 18th century thinking and grow in knowledge and understanding. There is help for you, but you have to take the first step and seek it. It hurts me to know that so many people continue to live in pain when relief is so near. I wish the happiness that I have found for those who still suffer.

"My prayer is that when anyone, anywhere, reaches out for help, let the hand of Alanon and Alateen always be there, and *Let it begin with me.*"



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The Legal Medicine Delegation to Russia and Estonia Report

*Daniel M. Avery, M.D.**

In 1993, the Ministry of Health of Russia and the Ministry of Health of Estonia extended an invitation to medical specialists from the United States to assist with their medicolegal reforms. This invitation was extended to the American College of Legal Medicine through the auspices of the Center for International Projects in Moscow.

It was my pleasure to be one of the physician delegates. The delegation was represented by a number of specialties of medicine as well as several lawyers. The delegation was directed by Dr. Charles R. Hollen, past president of the American College of Legal Medicine. The visit not only served as a goodwill mission, but an opportunity for exchange between professional counterparts and participation in historic changes currently taking place in the former Soviet Republics. The recent dissolution of the Union of Soviet Socialist Republics into separate states has intensified the desire for exchange as well as cooperation, help and support of Western professionals. The visit was an opportunity to focus on both the health care delivery system as well as the legal system. The delegation also was able to develop an effective international network of future exchange for professionals between both countries.

In the past, the Soviet health care system was completely supported by the state. A patient was able to present to a polyclinic or hospital and receive the appropriate care without any exchange of money. Unfortunately, the system has suffered from lack of funding, inadequate numbers of sufficiently trained doctors and nurses, corruption and shortages in antibiotics. Public health is a major problem in Russia. Since the 1980s, serious problems in the health care system have become evident and the newly organized states are struggling with how to restructure their health care systems in order to reverse a decline in health conditions in light of financial constraints and economic hardships.

Reports through the Russian literature over the past decade have reflected an increasing rate of infections, including many of the almost non-existent health care problems in the United States, such as whooping cough, diphtheria and polio. The Russian Ministry of Health estimates that over half of school children are in less than perfect health. Complications in deliveries occur in approximately half of all births. Since many women still deliver at home in the rural areas, the exact neonatal morbidity and mortality rates are unknown. It is projected that the maternal death rate is approximately five times higher than in the United States.

A number of factors relate to the poor health conditions, namely habits of the Soviet people — heavy smoking, poor diet, alcoholism and insufficient attention to fitness. Alcoholism remains a major health problem and the number of chronic alcoholics that die approach 20,000 per year. It has been said that there is no restricted age on drinking alcohol. Youths have easy access to alcohol, often seen in a drunken state on the streets of Russia. It has also been said that alcohol can be drunk in contrast to most of the water, which cannot. It kills most of the parasites, and unfortunately is used to fight depression from the horrible living conditions.

The general living conditions are poor. Sanitation is a major problem. In Russia alone, some 35,000,000 people live in cities where the air is dangerous to breath. More than 25% of the water is considered unsafe. A lot of the water comes directly from contaminated streams, rivers and lakes. Very few filtering systems are readily accessible.

Exposure to nuclear radiation is also a major problem, as evidenced by the fallout from Chernobyl. Over 1.3 million people have been officially regis-

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tered as having been exposed to radiation by that disaster. Russians living in the Urals were also exposed to radiation from Soviet nuclear weapons programs.

Unfortunately, the Soviet health care system was poorly equipped to meet these challenges in the past. Now that the trend is away from government supported health care, the challenge is even greater. It is expected that employers will have to buy health insurance, or contribute a certain percentage of one's income for health care. This is a new trend for the Russian people. They have not been accustomed to this in the past. It very probably reflects why about 70% of the general population would like to go back to the old Communist ways in which this was provided free of service.

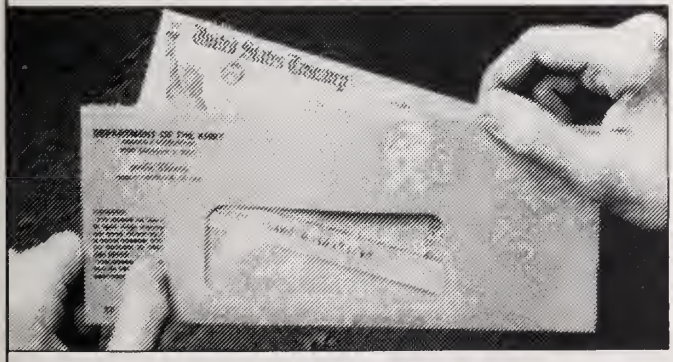
Allocation of resources is a major difficulty. The Soviet Union had three times as many hospital beds as the United States and twice as many doctors, but the life expectancy was five years shorter. Physicians are generally poorly trained. Hospitals have been dilapidated, overcrowded and unhygienic. Equipment was very scarce, antiquated and in poor repair. Medicines were in short supply.

It has been the trend not to import medicines from outside the country; so unless medicines and drugs can be produced within the confines of Russia, they generally were unavailable until recently. The health care system of education is also somewhat different from the United States. By age 15, one decides whether or not he wishes to be a physician. Medical school and college are combined into a six-year academic program, followed by a two-year internship. There are no final exams, registration, licensure, or specialization. It has been the case for those who wish to do sophisticated procedures to find someone who is able to do them and to work on an apprentice basis until they are able to perform the operation or procedure satisfactorily. However, one is free after two years of internship in most situations to practice if a hospital will accept him to do so. It is unfortunate that many of the physicians who leave Russia and go elsewhere are unable to pass licensing exams. Transfers out of the country are wrong with their diagnoses in some 69% of cases.

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It is unfortunate also that reimbursement for health care professionals is very low. The average doctor and nurse make $40 per month. In general, the more education one has, the less money he or she makes. This has been a long-standing effort on the part of the government to encourage many to be laborers without education so they will stay in the country and be happy. Generally, as one obtains more education and has abilities that could be used abroad, one is more likely to be interested in going to Western civilizations, i.e. Western Europe or the United States. Many of these never return, so as a deterrent to this, the more education one has, the less one makes. Unfortunately, in the hospital in Moscow we visited, the cleaning lady mopping the floor in the hall made more money than the Chief of Staff. One can imagine that this makes it very difficult for those to survive who are practicing medicine and is a major deterrent either to go into medicine or to at least stay in the country.

The hospitals are generally dilapidated and very overcrowded. Quarters are often cramped. Plaster is often falling out of the ceiling. 12% of hospitals have no running water. 42% of hospitals have no hot water. 18% have no sewage system. No hospital in Russia has any form of air conditioning and windows are often left open, even in the operating room for ventilation.

Much of the care in rural areas is performed by what is the counterpart of the American nurse practitioner, or midwife. These are called "fielders." These people are usually responsible for immunizations, primary care, normal childbirth and minor surgery. Patients are transferred to a hospital only if they cannot be cared for in this setting. Because the infection rate is high, antibiotics hard to find, pain medicine is difficult to obtain, and adequate obstetricians are few and far between, most women still deliver in their homes outside of major cities. This is with the assistance of midwives or fielders, mothers and grandmothers.

Another major issue is that of contraception. Contraceptives are generally not available. Russian men are not attuned to using condoms. The most popular method of birth control is termination of pregnancy or abortion as we know it. This must be done before 12 weeks of gestation and is paid for by the state. It is unfortunate that the state will not pay for oral contraceptives and avoid a surgical procedure with its attendant risks and infection.

Estonia thus far has retained its old system of free health care, although there is talk of change, including medical insurance and employee benefits for health. Unfortunately in the past many physicians have left Estonia for better working conditions in Finland and other areas in Europe.

The medicolegal reforms in Russia and Estonia as well as the other commonwealth of independent states are a formidable task. Much work remains to be done. Generally the health system is described as comparable to the United States in the pre-depression era. The City Hospital in Tallin hopes to start residency programs for certification and appropriate training in the medical specialties next year. The American College of Legal Medicine and the Center for International Projects will continue to work with them in this endeavor. Participation with other countries as well as foreign exchange with other health care systems will also allow physicians to become better equipped and better educated to deal with the health problems. Sole provision of care is not the only challenge. Administration of that care, funding and legal measures to control it remain a terrific challenge to the Russian and Estonian people as well. While many changes are occurring in the legal independence of the Russian states, medical health care need on a day by day basis is a must.

While the conditions are not satisfactory at all, I am encouraged about the endeavor on the part of those health care professionals who are working in the system to provide the very best care they can. With support of foreign nations and support by the Russian government, it seems feasible that a reasonable health care delivery system can be possible in time.

Mobile Wasn't First Medical School

Editor, *Alabama Medicine*:

On page 14 of the July issue of *Alabama Medicine* (vol. 63, number 1) there is a photograph of a plaque recently erected by the Medical Society of Mobile County telling of "The first medical school in Alabama and the thirty-fourth in the United States, ... established on this site in November, 1859."

Everyone should realize, of course, that there already exists a highway marker in Dadeville, Tallapoosa County, which claims to mark the site of the first medical school established in Alabama. That was the "Graefenberg Medical Institute of the State of Alabama," established in 1852 by Philip M. Shepard, who had an M.D. degree (two, in fact) from the Georgia Medical College. It was granted an official charter by the Alabama legislature, which stated that "the graduates of this Institute [are] entitled to all the privileges accorded to graduates of leading Medical Colleges." It was largely a family affair. P.M. Shepard was " 'proprietor and professor'; his half-brother, W. Banks, was appointed president of the Board of Trustees; another half-brother, J. T. Banks, and a cousin of Mrs. Shepard, M. L. Fielder, were named trustees. Dr. James I. Shackleford and William M. A. Mitchell rounded out the board, as Dr. Shepard had apparently exhausted his supply of relatives."[1] Shepard managed to graduate, among others, his three sons (who promptly joined the paid faculty) and one daughter, probably the first female to obtain a medical degree in Alabama.

It was a tough school. Final examinations administered by the Board of Trustees lasted three days and three nights, "often consisted of more than 5,000 questions," and were open to the public.[2] The school closed with the onset of the Civil War.

However, the Dadeville sign is not exactly correct, either.

A Thomsonian (i.e., herbal) medical school was opened in Wetumpka in 1844 by dissident faculty from the botanical medical school in Forsyth, Georgia. Another school, the Alabama Medical Institute, had received a state charter in 1844, and the herbalists joined it. This school operated one year, graduated one class, then closed, and the faculty moved on to greener pastures in Memphis, "and joined the staff of the newly chartered (1846) Botanico-Medical College of Memphis."[3]

Maybe the new plaque in Mobile refers to "the first *real* medical school" (i.e., one along European lines of the developing basic sciences). If so, then maybe UAB should put up another plaque. (It already has one sponsored by the historian Tennant S. Williams, Ph.D. The existing plaque at UAB is also a highway marker and includes a narrative of its predecessors, including the Mobile school.) However, since the medical school at UAB is the first four-year school in the state to be officially accredited, and therefore the first officially recognized by the AMA, surely something the Mobile society would want to take into consideration, the one at UAB must be "the first *real* medical school in the state."

As for being number 34, that's worth a whole book (maybe to somebody). Since in the old days medical schools came and went in even more shadowy less certain terms than the herbal school in Wetumpka, nobody knows exactly how many there were, or even how to count them. The highest estimate I've run across lately is that of David Rogers, M.D.: "By the late 1800s, we had 450 medical schools."[4]

But the real question that gnaws at the ulcers of historians, medical and otherwise, is: Who cares?

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[Dr. Pittman returned to Alabama in September.—Ed.]

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The Physician as a Commodity vs. His Role as Health-Care Manager

Jacques R. Caldwell, M.D.
Editor, Journal of Florida Medical Association

Those of us who have watched three decades slither away since our days in medical school mourn the derogation of the doctor that has occurred during this interval. The generic image of the physician has lost its well-scrubbed sheen and knight-like visage. Our generation expected a bequest of responsibilities and perks of a long-honored profession; instead we have inherited a patrimony of suspicion.

The reasons for devolution of physician esteem among the public are varied and have been reviewed multiple times in the media and in these pages. The demystification of medicine by the public's increased sophistication about medical matters and technology, the great leap in the cost of health care and the failure of physicians to live up to the Marcus Welby image are commonly cited.

Another reason, usually not mentioned, is that despoiling the physician image is profitable and has provided millions of jobs to a newly-risen class of medical care hangers-on. These are the people who never provide care but earn their living regulating, politicizing, administering, analyzing, suing and defending from suits those who provide medical care. Legions of untrained and unqualified people, whose numbers far exceed the total physician population, justify their being by insinuating themselves into the daily management of patients. This interference has defiled the sanctity of patient-physician privacy, confidentiality and trust.

The debasement of the special and trusting relationship between doctor and patient and escalating health-care costs have stimulated legislatures to permit independent medical practice by nonphysicians such as nurse practitioners, optometrists, physical therapists and other paramedical types. This trend has blurred the necessity for the value of doctor-directed care. The unproved impression exists that these practitioners deliver services of equal sophistication and quality but more inexpensively than do physicians.

The distinctions among the types of care given by physicians and paramedical practitioners evade some people. For instance, California Congressman Fortney "Pete" Stark, Chairman of the Health SubCommittee, warned doctors whom he addressed in Washington during March of this year that unless doctors reduced costs he would turn ophthalmologic care over to the optometrists and orthopedic care to chiropractors and podiatrists. Those of us who listened to a recording of his comments chuckled at the pretentiousness of his power-bloated bleatings but shuddered at the culpable vacuity of someone who has been granted so much responsibility for healthcare legislation.

The effacement of the value of physician training, work ethic and skills is reflected in physician reimbursement. Physicians providing purely diagnostic and management skills, such as pediatricians and some primary care physicians, are paid so poorly that they now earn less than a fourth level bureaucrat in Tallahassee. Managed care entities treat their physicians as commodities—as a mere cost item on their profit and loss sheet. By squeezing these expenditures they hope to increase their profitability and reduce the overall cost of medical care. (The fact is that this strategy has had the opposite effect; as they have reduced physician pay, their costs have escalated.)

Administrators of some hospitals have developed an openly hostile attitude towards their medical staffs. Others ignore physician requests for technological improvements, staffing changes that might improve patient care and alterations in the hospital infrastructure. These tactics have also been counterproductive since doctors have frequently rebelled and transferred their patient care to competing institutions.

Perhaps the ultimate insult to the profession is the exclusion of physicians from some of the decision making in government-induced health-care reform.

Governor Chiles has excluded doctors from the Community Health Purchasing Alliance (CHPA) boards. Hillary Clinton excluded all providers from her health-care reform task force. Society does not expect wisdom in its politicians but those two decisions to keep doctors away from the reform process are akin to designing a new airplane without an aeronautical engineer or seeking investment advice from someone whose own portfolio consists merely of a drawer full of discounted pizza coupons. The political forces of no other developed nation have designed a health-care system that is free of inflation rates similar or higher than ours (except for Japan—a country in which physicians own many of the clinics and hospitals).

Attempts to reduce the doctor to a commodity have not cured the ailments within the health-care system. Neither government nor business has been able to resolve problems of cost nor perceived problems of lack of access. If health-care planners would step aside and allow someone to dust away the dross of wishful thinking so that they could view the core of reality about health care, they would recognize that the vast majority of patients access medical care through a physician whom they trust and whose advice they follow. Physicians control the decisions regarding hospitalization, drug choice, and the need for technological services. Doctors own the key to the utilization of services. If health-care costs are to be contained some services will have to be reduced and only physicians can make those decisions for their individual patients. If society continues to devalue the physician's time, training and thinking then society will have to expend an increasing amount of money to prevent the doctor from utilizing the technology that today is often substituted for physician thought processing. It is technology, not the doctor or any other factor, that is driving most health-care inflation.[1]

The current confusion concerning the future structure of the American health-care system is an opportunity for physicians to regrab control of its direction. Managed care seems to remain a key component of any politically acceptable system; we can accept managed care but let us assure that doctors become the managers.

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to provide care cheaper than HMOs owned by insurance companies in California. Clinics without walls in which geographically dispersed physicians share common facilities have also provided an economically favorable health-care delivery structure.

A group of physicians in Volusia County has joined together in a network to provide care for employees and families of a Coalition consisting of the county school board, county government and community college. The administration of those three entities was dissatisfied with the managed care options within the county and requested that the doctors form a group to service their employees. The principle that drove the union of doctors with the employee groups was this: physicians would be reimbursed at a nondiscounted level for their services but would have to promise to control utilization. Secondarily, administrative hassle of the individual physician was to be minimized.

The Volusia County experiment permits patients to maintain their choice of doctors, including specialists. Primary care doctors are not subjected to the risks of capitation nor to the need to sign documents permitting patients to see specialists. Precertification review is currently managed by an outside company but during the first six months the necessity for prior approval for hospitalization or surgery has been dropped for many diagnoses and procedures. All decisions regarding appropriateness or the necessity of care [are] relegated to a physician panel. Governance of the physician group is performed by physicians elected by their peers. These managerial responsibilities consume time, require politic interactions with peers, and some sacrifice. However the Volusia County experience is containing health-care costs for the Coalition and physicians are being allowed to provide appropriate treatment to all their patients at a very reasonable level of reimbursement.

In summary, the attempts by business and government to treat physicians as commodities—as items as interchangeable as ingots of aluminum or bushels of wheat—have not controlled costs in the American health-care system. Rather the practice of excluding the physician from the health-care system managerial class has had a perverse and opposite effect—costs have been driven relentlessly upward. Perhaps it is time to rethink the role of physicians in the health-care process; perhaps planners should examine the wisdom of reducing the size of the nonphysician managerial "booboisie."[2] Most importantly doctors need to take advantage of the current chaos among health-care planners and implement their own health-care systems. Only systems for which physicians accept responsibility and share in the outcomes will prove cost-effective.

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Physicians Care Network

South Carolina Medical Association

INTRODUCTION

There can be no question that the health care system is on the threshold of massive change due to the pressure being brought by the American people, private business and the government. Proposals are being put forth from many sectors but to date none of these have included a physician-managed model. The proposal of the American Hospital Association advocates vertically integrated community care networks with the hospital as the pass-through point of all monies. This means the hospital will contract with purchasers and use that money to contract with other providers such as physicians for services to the network. A draft bill currently being considered by the Health Care Planning and Oversight Committee proposes that health Purchasing Cooperatives be developed to contract with Qualified Integrated Health Services Networks for the health needs of the members of the cooperatives. The problem with each of these models is that physicians will be reporting to some other entity.

With the future emphasis on managed care and integrated networks it is imperative that physicians organize themselves into some form of economic unit that will provide an opportunity to compete in the health care marketplace.

PHYSICIANS CARE NETWORK

The South Carolina Medical Association plans to organize a Physicians Care Network, an economic unit owned and operated by the members of the SCMA under the auspices of our subsidiary the South Carolina Medical Care Foundation. The objectives of this organization will be to allow physicians to:

1. compete in the health care marketplace for market share
2. negotiate for the provision of health care services to a variety of health care purchasers in an efficient and cost effective manner
3. provide high quality medical care
4. provide effective utilization review
5. share financial risks with purchasers
6. provide a mechanism for adequate reimbursement on a fee-for-service basis.

Physicians are currently becoming members of Health Maintenance Organizations, members of Preferred Provider Organizations and employees of hospitals. Hospitals are seeking to create their own community care networks by developing support from their governing boards, medical staffs and communities. They are even training physicians to sell the idea to other physicians. The Physicians Care Network gives the physician another alternative in which to lead the way as health system reform moves forward. The Physicians Care Network is not intended to be the only network for physicians and we encourage you to join all that meet your needs and those of your patients, but this will be the only statewide network operated by physicians in a risk sharing partnership with the purchasers.

The only other option besides the Physicians Care Network is to have physicians organized and controlled by hospitals, health insurers and purchasers.

OPERATION

The Physicians Care Network will be marketed only to self-insured groups initially and marketed as a provider/business partnership. Here is how it will work. Actuaries will calculate a target figure for each specific business. Once the target figure is established, the Physicians Care Network will offer to contract with that business on the following basis. The network will provide care for the following year with claims being paid to physicians at 100% of their charges up to the 88th percentile of the usual and customary fees. A withhold of 15% will be held back from the provider on a company-specific basis until an assessment can be made regarding the actual aggregate cost of care versus the target figure. There are three possible outcomes: If the target is met, the providers will be reimbursed the full withhold minus a small assessment to cover operational costs. If the target is exceeded, the company will be reimbursed out of the 15% withhold up to the amount withheld minus the management fee. If the cost of care comes

in below the target figure, the providers will be reimbursed the full withhold minus a small percentage for operational costs and the company and the providers will share the surplus. It is this risk sharing arrangement that make this a provider/business partnership.

In addition. data from the utilization review system will be provided to the business along with physician input regarding the benefit design of their health plans.

It must be emphasized that to make this work there has to be serious utilization review. It has long been the contention of business, the insurance industry and utilization review companies that physicians performing review is like the fox watching the hen house. To dispel this notion, the network physicians are putting a percentage of their earnings on the line. Providers who are unwilling or unable to conform to the utilization review standards of the network after being notified three times, will be dropped. This type of decision will be made by the Utilization Review Committee made up of the physicians' peers who participate in the network and upon the recommendation of the Medical Director.

Operations will begin by recruiting the network physicians. In order to join the network, the physician must meet two criteria, one is to be a member in good standing of the SCMA and two is to agree to submit to the network a copy of his/her current fee structure. A contract will be signed between the network and the physician. Concurrent with the recruitment of the network physicians several committees will be appointed and criteria for utilization review adopted. Once it becomes clear that the physicians of South Carolina are supporting the network and that there will be sufficient numbers to cover the state, we will begin marketing the network to businesses. Marketing will be done on a regional basis so that in some cases you may join the network but it may be some time before patients in your area will be covered.

ORGANIZATION

The organizational structure of the Physicians Care Network will consist of the network physicians, the network staff, a management/consulting company, and three committees. A policy committee will serve as the governing body and will bé made up of eight physicians, two representatives of business. a hospital administrator and a consulting advisor. A second committee will be the Utilization Review Committee which will be made up of 12 physicians. A third committee will be the Employers Advisory Committee consisting of four physicians, four businessmen whose companies are contracted with the network, a network hospital administrator and a consultant advisor. All committees will be appointed by the SCMA Board of Trustees and serve at their pleasure.

Staff of the network will be direct employees or contractors depending on the staff function. The staff functions will be management, communications, marketing, utilization review, claims administration, actuarial and financial services and secretarial /clerical.

HOSPITALS

The network will solicit the participation of hospitals and there is no reason for them not to join unless of course they have a competing network. Currently the managed care plans contract with hospitals for significant discounts in return for market share but hospitals do not share in the profits of these groups. What the Physicians Care Network will offer is a chance to recover more than they charge by sharing in the risk. Hospitals will be approached one by one as the network grows.

FINANCE

As was pointed out earlier in this document, the network will hold a small percentage of the providers' withhold for operational expenses. In addition, each company that contracts with the network will pay an access fee for using the network. the access fee will be calculated on a per employee per month basis.

Financing for the startup costs will be covered by a $250,000 loan being made by the SCMA to the Foundation that will be repaid from future revenues.

TIMETABLE

Following the general membership meeting the implementation phase will begin. We hope to be able to accelerate the process in order to have the network functioning within six to nine months. A progress report will be provided at the annual meeting.

CONCLUSION

During the past decade there have been numerous papers, reports, plans and proposals, all of which identified the problem but depended on government action or government money to be implemented. The Physicians Care Network requires only a commitment from physicians to make it a success. If we succeed we will have demonstrated that radical change is not necessary and that health care providers cannot only compete in the marketplace but force others to do the same. The choice is competition versus control.

PRIOR HEALTH CARE CLAIMS EXPENSE $1,100,000
TARGET CLAIMS EXPENSE $1,000,000

	BUDGET	
MEDICAL	(42%)	$420,000
HOSPITAL	(38%)	380,000
Rx/OTHER	(7%)	70,000
ADMIN/CORP O.H.	(13%)	130,000
		$1 ,000,000

HEALTH CARE CLAIMS PROJECTIONS $1,100,000
TARGET CLAIMS EXPENSE $1,000,000

EXAMPLE A

ACTUAL EXPENSE		$1,000,000
LOSSES OVER TARGET		0
PROVIDER RESERVE		
PERCENT OF CHARGES	15%	$120,000
OPERATING COST RESERVES	3%	- 24,000
NET RESERVES AT RISK	12%	$96,000
ADJUSTMENT FOR NET LOSSES:		
NET AT RISK		$96,000
NET LOSSES		- 0
PRO RATA DISTRIBUTION		$96,000

ALL AT RISK FUNDS FROM MEDICAL/HOSPITAL SERVICES

***For illustrative purposes only, the assumptions above assume that th Provider Contingency Reserve does not change with the company's actual expenses.

HEALTH CARE CLAIMS PROJECTIONS $1,100,000
TARGET CLAIMS EXPENSE $1,000,000

EXAMPLE B

ACTUAL EXPENSE		$1,050,000
LOSSES OVER TARGET		50,000
PROVIDER RESERVE		
PERCENT OF CHARGES	15%	$ 120,000
OPERATING COSTRESERVES	3%	- 24,000
NET RESERVES AT RISK		$ 96,000
ADJUSTMENTS FOR NET LOSSES:		
NET AT RISK		$ 96,000
NET LOSSES		- 50,000
PRO RATA DISTRIBUTION		$ 46,000

***For illustrative purposes only, the assumptions above assume that the Provider Contingency Reserve does not change with the company's actual expenses.

HEALTH CARE CLAIMS PROJECTIONS $1,100,000
TARGET CLAIMS EXPENSE $1,000,000

EXAMPLE C

ACTUAL EXPENSE		$ 950,000
SURPLUS UNDER TARGET		50,000
PROVIDER RESERVE		
PERCENT OF CHARGES	15%	$ 120,000
OPERATING COST RESERVES	3%	- 24,000
NET RESERVES AT RISK		$ 96,000
ADJUSTMENT FOR NET SURPLUS:		
NET SURPLUS		$ 50,000
NET AT RISK		- 0
AVAILABLE SURPLUS FOR DISTRIBUTION		$ 50,000
(PCN PROVIDERS - $25,000; COMPANY - $ 25,000)		
PRO RATA DISTRIBUTION		$121,000

***For iilustrative purposes only, the assumptions above assume that the Provider Contingency Reserve does not change with the company's actual expenses.

HEALTH CARE CLAIMS PROJECTIONS $1,000,000
TARGET CLAIMS EXPENSE $1,000,000

EXAMPLE D

ACTUAL EXPENSE		$800,000
SURPLUS UNDER TARGET		200,000
PROVIDER RESERVE		
PERCENT OF CHARGES	15%	$120,000
OPERATING COST RESERVES	3%	- 24,000
NET RESERVES AT RISK		$ 96,000
ADJUSTMENT FOR NET SURPLUS:		
NET SURPLUS		$200,000
NET AT RISK		- 0
AVAILABLE SURPLUS FOR DISTRIBUTION		$200,000
(PCN PROVIDERS, $96,000; COMPANY, $104,000)		
PRO RATA DISTRIBUTION		$192,000

***For illustrative purposes only, the assumptions above assume that the Provider Contingency Reserve does not change with the company's actua expenses.

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Mrs. William Hall
A-MASA, President

Crisis Is Disguised Opportunity

The following article is provided by Anne Marie Gormley of Montgomery. Anne Marie is the Legislation/AlaPac/Am/Pac chairperson for the Auxiliary.

Through her efforts the Auxiliary stays informed as we increase our memberships legislative education networking and involvement.

If your county medical Auxiliary or Society would like to schedule a Legislative workshop please contact Anne Marie at 288-1489 or Linda Hall 343-0545.

Ok, Ok, I know you are sick to death of hearing about health system reform. All we have heard for months and months are the media's version of "rumors and innuendœs" about the activities of Hillary's Health Task Force, cloaked in secrecy, supposedly to keep the "special interest" groups out of the loop. Do you get the feeling that you are about to be sacrificed to the Gods? As Hillary herself put it, "If I read only what was in the newspapers, I'd be scared, too."

Last month, I, along with seven outstanding auxilians, had the honor and privilege of representing our great state at the AMA Alliance (formerly Auxiliary) House of Delegates in Chicago. It was a life-altering experience, as we attended the AMA House of Delegates opening session, which the First Lady addressed. We also saw such inspirational speakers as Cokie Roberts of ABC News and Beverly Sills. During the course of the session, I was honored to be among highly talented, motivated and skilled spouses. Excellent examples are the Florida Medical Society Alliance, which helped their medical association in their efforts to protect their patients' interests in the major health care system reform; and those from Kansas, whose campaign efforts resulted in the election of four physician spouses and one physician to their state legislature.

A-MASA members are ready, willing, and able to rally around our spouses to safeguard that sacred doctor-patient relationship in the political arena. I have been working closely with MASA's governmental affairs department developing the ACT program. ACT stands for Activate the medical community, Communicate its message, and Teach its members.

We will activate the medical community by developing a grassroots computer program comprised of physicians, spouses and office administrators. This system will be set up to provide immediate information for members to be able to respond adequately to pertinent legislative issues upon MASA's request. Auxiliary members also will be available to work actively on campaigns for "physician friendly" candidates across the state.

In 1994, Alabama's seven congressman, the entire state legislature, comprising 140 members, as well as our governor, will be campaigning for re-election. And yes, we can make an impact on the outcome of these elections with our AMPAC and ALAPAC contributions.

We will be able to communicate our message to policymakers through mini-internship programs, the grassroots system, and days at the legislature. Many county societies have successfully completed mini-internship programs and many more plan to this year. The auxiliary can be a terrific asset to this program.

Teaching our members how to communicate our message is the final step in the process. I *truly* believe our members want to be politically

active, but are not quite sure how to go about it or what to do. *Knowledge is power.* As I continually remind auxiliary members in legislative grassroots lobbying workshops, if you have ever been skeptical of the power of grassroots lobbying, just watch the AARP in action. Dare the politicians tinker with Medicare and Social Security benefits! They know the results of that! Thousands of calls and letters from angry, well-informed senior citizens.

From my experience working for Senator Larry Pressler (R-SD), I witnessed first hand just how sensitive elected officials are to constituent views. I also learned a lot about grassroots lobbying from Andrew Manatos, former Assistant Secretary of Commerce. After his stint in the Carter administration, Andy formed a very successful lobbying firm that represented the interests of Greece and Greek Americans. I had the good fortune to work for Andy after I left Senator Pressler's office.

He was quite skilled at organizing a well-connected and highly motived grassroots network of Greek Americans who were very active in their state legislatures and Congress. He considered constituents who communicated through phone calls and letters, along with financial support, to wield the greatest influence on the political process.

So, our beloved spouses, let's just review a few reasons why you don't feel *you* can be politically active. Let's get those out of the way right now. My husband was the world's worst cynic, so I can handle any of you.

1. "Sure the AARP can lobby effectively — are retired and have all the time in the world to devote to protecting their interests." I say to you — the auxiliary members and office administrators, who help you keep organized and on time, can help you with that. Sure, auxiliary members are busy people, but often we have flexibility in our schedules and a fair amount of time. Some auxiliary members work in their spouse's office so that helps even more! Yes, Hillary acknowledged that you spend at least 80 hours a month on paper-work, but let's not wait for her to do something about it!

2. "How can one person make a difference?" Usually, one person alone can't really make a difference. Although, I have seen it happen with a letter to the editor. One person getting *others* to respond makes the difference. Your auxiliary members will be there for you! Add money to where your mouth is and look out. There is no telling what you can accomplish.

3. "Yes, I would like to be politically active, but I don't know how to go about it." The auxiliary, under the direction of MASA's governmental affairs department, will take care of that, too.

So, please, let's face that sinking feeling head on and look within ourselves to a solution to the problem. *You* are a needed commodity — medicine cannot be practiced without physicians. *You* are among the brightest and most educated citizens in this country. The greatest love an auxilian can show his or her spouse is to be politically active and fight this war in unity. This crisis is an opportunity in disguise. *We* can solve it together.

Presidents Page *continued from page 4*

ly, by specialty and by region.

Nationwide, 63.8% of all physicians provided charity care. In our region, the percentage was somewhat above that —66.2%. Nationally, doctors provided an average of 3.0 hours per week in free care and 3.6 hours of reduced-fee care for a total of 6.6 hours per week. Physicians here in the Deep South contributed roughly the same amount of time to those who could not pay or could pay but little.

By specialty, surgeons and general/family practice doctors participated in charity care at a higher rate (about 71%) and, of the two groups, surgeons donated the most time per week, 7.7 hours on average.

As you might expect, physicians in rural settings had a higher national rate of charity care participation among all doctors.

Overall, in all specialties and all regions, American physicians providing charity care donated 10.6% of their total practice time to the medically indigent or those of limited means.

The 1989 value of these services nationwide was $6.8 billion. I suspect the numbers have risen sharply in recent years because of the economy and the number of Americans losing their insurance coverage for one reason or another.

As the health reform debate heats up, the above figures are not likely to be among those splashed on page 1 or displayed on the nightly news. There is a kind of Gresham's Law of information: bad news drives good news out of the marketplace of ideas.

Sadly, I do not expect that law to be repealed in the coming conniptions in Washington. Get ready to don your black hats.

But remember: You can make a difference.

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Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

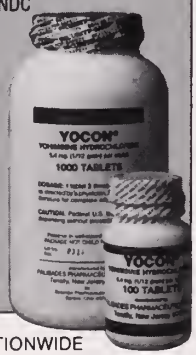
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-moditying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, penpheral neuropathy, penpheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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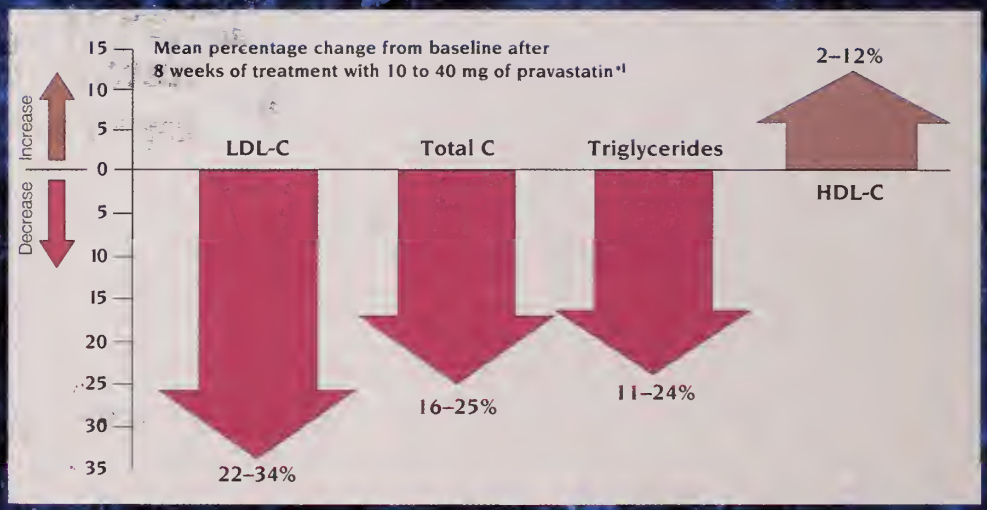
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol*. 1991;14:146-151.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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Alabama Medicine

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

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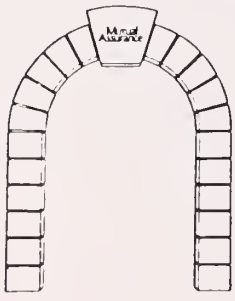
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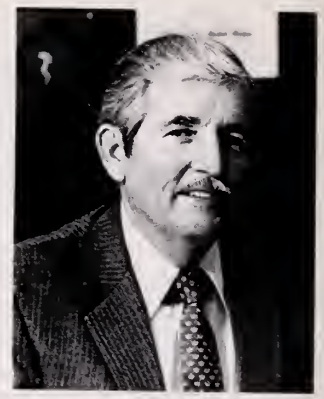
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

The Enemy Redefined: Normality

There have been so many learned treatises lately on the substantive issues involved in health care reform, I have decided to take a break. For the present, I will leave the foreground to others while I move to the background against which this debate will dominate much of the national agenda next year.

In the assessment of many perceptive observers, the United States is in a troubled and troubling period. With the collapse of the Soviet empire, this country lost its central driving force — saving the world from the communist menace. The cold war was incredibly expensive; the arms race literally forced the Soviet Union into bankruptcy and left this country with a debt so huge that the average mind simply cannot comprehend it. At least, I can't: $4.4 trillion doesn't compute for me, not even when I extend it by the appropriate number of zeroes — $4,400,000,000,000.

But there is an even greater debt, and it is this one that could well destroy the America of song and story. And that is the persistent degradation of the national character. We have squandered it every bit as recklessly as we have squandered our treasury and with potentially more disastrous results over the long haul.

We no longer know who we are; our ideas of conduct, of moral imperatives, the very concept of what is good or bad — all have been so systematically attacked since the 1960s that what remains of the once celebrated "American character" is a hollow shell of its former grandeur. In fact, the very idea that there is, or was, an American character would start a riot on many of the nation's campuses today; there, the fashion is a total repudiation of the advances of Western civilization.

The most remarkable aspect of the times is that every faction or group claiming special status has been victimized by "the system," by society, by persecution, no matter how far in the distant past. Organizations of victims dominate national discourse; unless you can claim victim status there is no forum for you. The group has replaced the individual as the primary unit, and the group is concerned less with achievement than with grievances. Cloaked in self-pity, various victim groups have intimidated great universities into campus censorship of any word or deed that might upset them or question the legitimacy of their victim posture. They have successfully demanded not freedom of speech, one of the bedrock beliefs of our society, but freedom *from* speech. Similarly, they have forced timid administrations to throw out curricula and give them courses of their own design, usually as remote from true education as can be imagined.

But it gets worse. Writing in the *American Scholar,* Senator Daniel Patrick Moynihan, who has often ventured where others fear to tread, devotes his considerable powers of insightful thinking to what he calls "Defining Deviancy Down." Using deviancy in the broadest sense, he argues that in any current social epidemic — whether violent crime, family breakdown, mental illness — the country has been so helpless that we have adopted a form of denial that deals with the epidemic by defining away most of the disease. We are persistently lowering the threshold of what we call normal.

In the last decade, for example, the incidence of single parenthood has more than tripled, so that today

30% of all American children are born to unmarried mothers, with all the ramifications this portends in poverty, welfare dependency, and crime. This has become a monstrous national problem. Yet social workers, phony intellectuals and the mass media have redefined this deviancy as simply another lifestyle choice.

Senator Moynihan's second example is crime. We have become inured to levels of criminality that would have been considered intolerable 30 years ago, he writes. His article was written before the latest outrage from the West Coast but too many people excused those who tried to kill a truck driver during the L.A. riots because the homicidal thugs were, after all, expressing their indignation over the Rodney King verdict and thus not accountable for their savagery. They were simply engaged in the constitutional right of social protest, which now includes attempted murder. Remember, they not only beat their helpless victim without remorse but tried to bash his brains out with a brick.

The truck driver's brutal assailants, whose vicious acts all of us have seen from the helicopter TV shots, were only slightly obsessive in their behavior, we are asked to believe. And, being black, they could not have been motivated by racial hatred for their white victim since that is a unilateral sin.

Murder, a way of life now in many neighborhoods, is reported much like traffic accidents. When the mayor of the nation's capital asked for National Guard troops to help contain the relentless slaughter in her city, she was ridiculed by many as being overly excited by the lifestyle of recreational killers who have been victimized by society's neglect. At least one minority leader chided the mayor for not demanding more parks and playgrounds and better housing instead of the troops.

The point being this: the mayor's acute distress over the carnage is old-fashioned and reactionary. The mayor seems to have forgotten the new commandment — you don't punish criminals; you reward them.

Senator Moynihan cites our absurd attitude toward the mentally ill, who now crowd the streets of major cities, sleep in doorways of buildings, and often terrorize passersby. In 1955, New York asylums had 93,000 patients. Last year there were 11,000. The others, and their descendants, having opted for an alternative lifestyle, which was once called an intolerable public nuisance. Those who defend the right of pathetic babbling vagrants to spread tuberculosis and other diseases say they are just poor, not crazy. And even if they are crazy, that is just another lifestyle.



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Senator Moynihan contends, and I agree, that the sociologists and bleeding hearts have succeeded in moving normal behavior downward to the extent that deviancy has all but disappeared from public condemnation.

Writing in *The New Republic*, Charles Krauthammer embraces the Moynihan thesis but adds his own view that deviancy is not only being redefined down but up as well. (Mr. Krauthammner is actually Dr. Krauthammer, a psychiatrist who retired to write. His essays on a great variety of subjects have appeared in many national publications but he never affixes his M.D. degree and studiously avoids being typed. Only rarely does he reveal his background and then only to clear the air of any response accusing him of concealing his bias. I would call him a responsible, moderate conservative, but one who ventures occasionally to the near right and the near left as the mood strikes him. In sum, he wears no man's collar and is the exact opposite of a doctrinaire ideologue. He's an old-fashioned free thinker.) Mr. Krauthammer:

"Moynihan is right. But it is only half the story. There is a complementary social phenomenon that

goes with defining deviancy down. As part of the vast social project of moral leveling, it is not enough for the deviant to be normalized. The normal must be found to be deviant. Therefore, while for the criminals and the crazies deviancy has been defined down (the bar defining normality has been lowered), for the ordinary bourgeois deviancy has been defined up (the bar defining normality has been raised).

"Large areas of ordinary behavior hitherto considered benign have had their threshold radically redefined up, so that once innocent behavior now stands condemned as a deviant. Normal middle-class life then stands exposed as the true home of violence and abuse and a whole catalog of aberrant acting and thinking."

Those middle-class normal people who have hitherto been considered pillars of their communities, systematically engage in child abuse and spouse abuse, and indulge in politically incorrect speech and thought. Normal behavior is camouflage for all manner of newly defined and endlessly sensationalized charges by sociologists and by the media. Mr. Krauthammer:

"The moral deconstruction of middle class normality is a vast project. Fortunately, thousands of volunteers are working the case. By defining deviancy up they have scored some notable successes. Three in particular. And precisely the areas Moynihan identified: family life, crime, and thought disorders."

What follows is a brilliant exegesis of the moral leveling movement. Unfortunately, it is much too lengthy to summarize here. A brief sampling must suffice:

"Child abuse is both a crime and a tragedy, but is it 19 times more prevalent today than it was 30 years ago [as the statistics claim]?" Over-reporting is rampant, he says, just as under-reporting violent crime is rampant in the opposite direction. People with emotional problems in mid-life are actively encouraged to believe — and thus many do believe—they were sexually abused as children. If they have no memory of such abuse, some therapists encourage them to believe that they are repressing the memory. In other words, no recollection proves the case.

"The new psychology is rooted in and reinforces current notions about the pathology of normal family life... Nowadays neurosis is the outcome not of innocent errors but of criminal acts occurring in the very bosom of the ordinary-looking family. Seek and ye shall find: the sins of the fathers are visible in the miserable lives of the children. Child abuse is the crime waiting only to be discovered with, of course, the proper therapeutic guidance and bedtime reading."

Mr. Krauthammer then turns to second pillar of everyday bourgeois life: the ordinary heterosexual relationship:

"A second vast category of human behavior that until recently was considered rather normal has had its threshold for normalcy redefined up so as to render much of it deviant. Again, we start with a real offense: rape. It used to be understood as involving the use of or threat of force. No longer. It has now been expanded by the concept of date rape to encompass an enormous continent of behavior that had been viewed as normal or ill-mannered, but certainly not rape."

He quotes a recent newscast: "Some 47% of women are victims of rape or attempted rape...." A third of Stanford's women students claim to have been raped. And so on. But FBI data gathered under the Student Right-to-Know and Campus Security Act of 1990 found no reports of rape of any kind at Barnard College, a hotbed of anti-rape activity, or Harvard, Yale or Princeton, Antioch and so on. What is going on out at Stanford?, one might ask.

A study by Mary Koss, published in *Ms.* magazine, is the most widely cited authority for the rape epidemic. She found that nationwide 15% of college women had been raped and another 12% subjected to attempted rape.

Mr. Krauthammer: "In the Koss study 73% of the women she labeled as rape victims did not consider themselves to have been raped. Fully 42% had further sexual relations with the so-called rapist.... Something is wrong here..."

He goes on to thought crimes. The FBI is now doing background checks on prospective government employees to determine if they have ever told (or enjoyed) racial jokes, ethnic jokes, gender jokes, since these would be proof of thought deviancy and thus disqualifying.

"A University of Michigan student ... offers the opinion in class that homosexuality is an illness, and finds himself hauled before a formal university hearing on charges of harassing students on the basis of sexual orientation.

"The irony here is quite complete. It used to be that homosexuality was considered deviant. But now that it has been declared a simple lifestyle choice, those who are not current with the new definitions, and have the misfortune to say so in public, find themselves suspected of deviancy... Under the new dispensation it is not insanity but insensitivity that is the true

sign of deviant thinking."

A psychotic is free to rave in the middle of Broadway, but a student who calls a bunch of boisterous sorority students "water buffalo" is threatened with expulsion unless he submits to treatment for his deviancy.

Another myth debunked: "The mentally ill are not really ill. They just lack housing. It is the rest of us who are guilty of disordered thinking for harboring — beneath the bland niceties of middle-class life — racist, misogynist, homophobic, and other corrupt and corrupting insensitivities.

"Ordinary criminality we are learning to live with. What we are learning we cannot live with is the heretofore unrecognized violence against women that lurks beneath the facade of ordinary, seemingly benign, heterosexual relations."

And finally,

"... the perfect vehicle for exposing the rottenness of bourgeois life is defining deviancy up. After all, the law-abiding middle classes define their own virtues in contrast to the deviant, a contrast publicly dramatized by opprobrium, ostracism, and punishment. And now it turns out that this great contrast between normality and deviance is a farce. The real deviants... are those who carry the mask of sanity, the middle classes living in their cozy suburban streets, abusing their children, violating their women and harboring deep inside them the most unholy thoughts.

"Helpless in the face of the explosion of real criminality ... we satisfy our crime-fighting needs with a crusade against date rape. Like looking for your lost wallet under the street lamp, even though you lost it elsewhere, this job is easier even if not terribly relevant to the problem at hand...

"These new crusades do nothing of course about real criminality or lunacy. But they make us feel that we are making inroads on deviancy nonetheless... Having giving up fighting the real thing, we can't give up the fight. So we fight the new deviancy with satisfying vigor. That it is largely a phantom seems not to matter at all."

The prevalence of such mass idiocy as Moynihan and Krauthammer describe does nothing to reassure me that the national health care reform debate will be rational.

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PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

The Funny Money Game

It's well that Americans are suspicious of numbers, particularly those generated for Congress or the White House. Political partisans use number projections the way the legendary village drunk used lamp posts — for support rather than illumination.

Mr. Clinton had painted himself into a corner in his campaign rhetoric. He had told the people, in words or substance, that he would produce a bill within 100 days of his inauguration that would provide health care for the nation's uninsured by the simple expedient of eliminating waste. All gain, no pain.

It took the President somewhat longer than 100 days to hand Congress a 1,400-page bill that professes to achieve that objective, at least in part. Of course it does not. Although his principal source of funding is Medicare, which would be taxed some $189 billion, that's the same old shell game Congress has been playing for years to "balance" the budget.

That trick consists of taking future liabilities — that is, the predicted expenditures on Medicare — and relabeling these as fungible, present assets to be spent like play money. It is the exact opposite of accounting rule 106, which has forced corporations to charge future liabilities in retiree health care against present earnings.

I'm not an economist, but here is the silly analogy that occurs to me:

I decide I absolutely must have a luxury yacht. It was Commodore Vanderbilt, I believe, who once said if you have to ask how much a yacht costs, you can't afford one. So I don't plan to ask. I learned how to deal from President Clinton.

At the yacht showroom, I pick out one that seems suitably ostentatious for my expensive tastes. It is appointed with solid gold fittings; hand-carved exotic woods; onyx and select Italian marble sinks; every electronic gadget I could ever dream of, including over-the-horizon radar and satellite navigational aids; wide screen, high-definition TV in every room; a helicopter on the poopdeck in case I should develop the sudden urge to return to shore; fully automatic fishing gear that locates and catches fish for me, lies about the weight, and ices down the catch untouched by human hands; and so on. We're talking class, my friends. In short, a nice little boat.

I tell the salesman I'll take it. Rubbing his hands in anticipation of the killing he is about to make, he tells me that the company has a special on this week: Every yacht buyer will be given a once-in-a-lifetime chance to buy a luxury 90-room villa on the French Riviera at a fraction of its market value.

Well, I demur, that might be stretching my finances a bit. Then the brilliant Clintonomics thought occurs: I point to a somewhat less luxurious yacht (it has no automatic fishing gear but I tell the salesman I can rough it) and ask what the combined price of the villa and the middle-of-the-line No. 2 yacht would be.

Can you believe it: I can get both for the price of the No. 1 yacht I first selected. I congratulate myself for being a pretty canny yacht shopper. I figure I've pulled one on the salesman and quickly accept the offer.

I hastily sign the sales contract. Then, almost apologetically, the salesman asks me how I would prefer to pay for my purchase. By this time, of course, I have the yacht in tow behind my faithful gray

Buick. Pulling out of the yacht garage (or whatever it is yachts are kept in), and in my best condescending tone, I inform him that I have already paid him — in the money I didn't spend on the No. 1 yacht. Then, I'm gone, leaving the bewildered salesman eating dust.

Question: how long will it take the sheriff's posse to overtake me racing down the highway?

Absurd as this may sound, this is, at bottom, Mr. Clinton's principal financing plan. He proposes trading what he sees as a luxuriously wasteful Medicare five or six years down the road for a more modest Medicare and universal coverage in the near term.

I disagree with the President about a lot of things, but I know he is not that stupid. If he has all the compassion he professes to have for Americans, he must know that Medicare recipients, at the most vulnerable time in their lives, are already being shorted, since Congress has, time and again, cut their funding to the bone.

It was for that reason that the American Medical Association solicited, and received, the endorsements of every state society in support of a broad-based general tax in lieu of another radical and perhaps fatal axing of the quarter-century-old program for the aged and handicapped.

As this is written, the back-channel news out of Washington is that Clinton privately agrees with the AMA proposal. He could not propose a general tax, it is believed, because of the expected anti-tax backlash. But he is said to favor that if there can be a bipartisan summit meeting to share the burden of telling Americans that, for one reason or another, the price of that 1992 free lunch has just been increased.

As the months of committee haggling go by, I expect the reality of that decision to appear more and more inescapable. Thus will emerge the big question for both parties: will the public buy it? That will be the true test of Mr. Clinton's (and Mrs. Clinton's) powers of persuasion.

Unless there is realistic additional financing, over and above what employers, employees and cigaret smokers will pay, and/or heavy rationing, universal coverage is a sham.



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AIR FORCE

Diabetic Retinopathy And Visual Loss —

The Primary Care Physician's Role in Treatment and Prevention

*Richard M. Feist, M.D.**
Milton F. White, Jr., M.D.

Abstract

Diabetic retinopathy is estimated to cause blindness in 250 Alabamians each year. While diabetic retinopathy was once largely untreatable current therapies offer a 90% reduction in the rate of blindness. Common misperception of the preventable and treatable nature of this disease has unfortunately led to avoidable, permanent blindness in many patients. Because the early, treatable stages of diabetic retinopathy are often asymptomatic, timely ophthalmic evaluation and treatment are essential. The prevention of blindness in these patients requires the understanding by primary care physicians of the cause, findings and treatment of diabetic retinopathy. The purpose of this article is to define the terminology used in the description of diabetic retinopathy, describe the various indications for treatment, and to review the current screening recommendations of the American Academy of Ophthalmology. These recommendations include initial eye examination 5 years following onset of diabetes in patients 30 years or younger at the time of diagnosis and initial eye examination at the time of diagnosis in patients 31 years or older at the time of diagnosis.

Introduction

Diabetes mellitus is an endocrine abnormality in which either abnormally low insulin production (type I or insulin-dependent) or abnormal peripheral receptor resistance to normal or subnormal insulin levels (type II or non-insulin dependent) leads to chronic hyperglycemia with a myriad of complications.

Diabetes mellitus has been estimated to effect about 14 million Americans. Seven million Americans (about 3% of the population) have been diagnosed;[1] diabetic retinopathy is the leading cause of legal blindness in Americans between the ages of 20 to 74.[2] An estimated 250,000 Alabamians have diabetes but only half of these patients have been diagnosed. Diabetes mellitus contributes to the death of over 2,000 Alabamians each year and to 250 cases of blindness each year. Diabetes is estimated to cost $375 million yearly in Alabama in direct medical costs and lost productivity.[1]

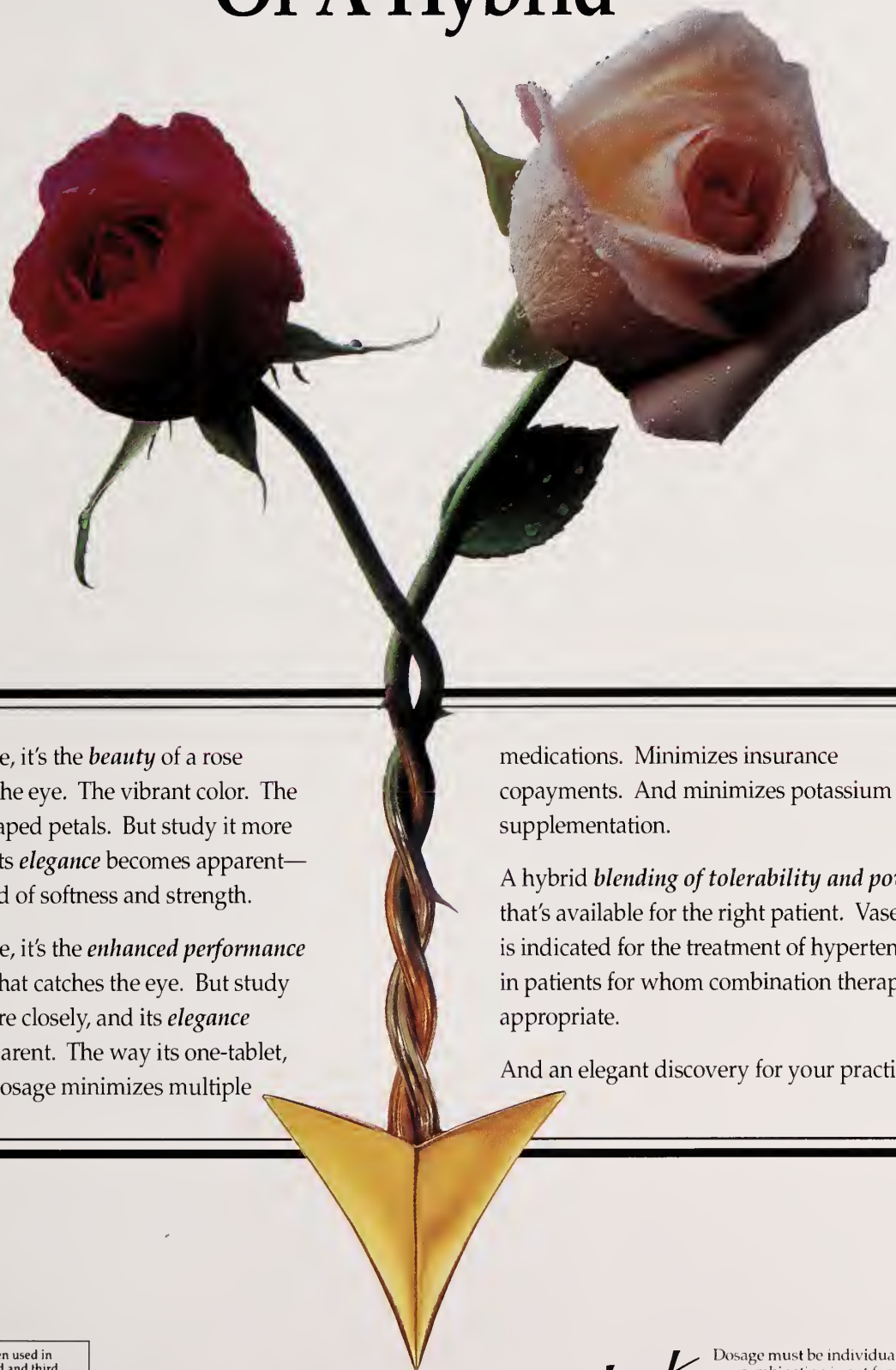
Prior to the discovery of insulin and other hypoglycemic agents the life expectancy of patients with type I diabetes was typically quite short and life expectancy was often shortened as well in patients with type II diabetes. Frederick G. Banting and Charles H. Best discovered insulin in 1921. With the advent of medical therapy for hyperglycemia, previously unappreciated chronic complications of diabetes began to emerge. One of the most severe of these complications is diabetic retinopathy.[3]

Etiology

Diabetic retinopathy primarily affects the retinal blood vessels. Chronic hyperglycemia leads to a number of changes in the retinal capillary bed; these changes which include loss of capillary pericyte cells and thickening of the capillary basement membrane lead to increased capillary permeability and to irreversible capillary closure. Areas of capillary closure in the equatorial and midperipheral retina are a universal finding, underlying all of the changes of background and proliferative diabetic retinopathy. While the most extensive capillary closure in diabetic retinopathy occurs peripherally, the clinical findings

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USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

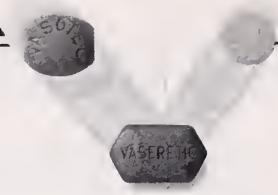
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Enalapril Maleate-Hydrochlorothiazide

Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)



USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General: Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy: Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses, 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate: Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5.6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate: Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent preexisting renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients: Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions: Enalapril Maleate: Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide: When administered concurrently the following drugs may interact with thiazide diuretics.

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagenicity assay with or without metabolic activation. Enalapril was also negative in the following genotoxicity assays: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain, *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings: Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*), pulmonary embolism and infarction; pulmonary edema, rhythm disturbances including atrial tachycardia and bradycardia; atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported; a causal relationship to enalapril has not been established. *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness. *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia. *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia. *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions. *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness. *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS). *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia. *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

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typically occur in the central retina, specifically the macula (which is responsible for the formation of central vision) and adjacent areas of retina.[3,4]

Background Diabetic Retinopathy

The earliest changes of diabetic retinopathy visible on fundus examination are microaneurysms. These small outpouchings of retinal capillaries are usually asymptomatic but may be associated with sufficient fluid leakage to lead to surrounding retinal thickening. Another early fundus finding in patients with background diabetic retinopathy is venous distension. Flame-shaped retinal hemorrhages are relatively superficial in the retina and occur from small hemorrhages into the nerve fiber layer of the retina. Blot and dot hemorrhages occur from bleeding in the deeper layers of the retina. Diabetic macular edema occurs from leakage of serous fluid into the macula, either from localized leakage from retinal capillary microaneurysms or from diffuse leakage adjacent to areas of capillary nonperfusion.

Yellowish-white focal collections of protein and lipid precipitates are seen in some, but not all, cases of diabetic macular edema (Figure 1). Called hard exudates, these precipitates tend to occur in the macula.[4]

Clinically significant diabetic macular edema is defined as thickening of the retina within 500 microns (0.5mm) of the center of the macula, thickening of the retina associated with proteinlipid exudates within 500 microns of the center of the macula, or thickening of the retina 1,500 microns (1.5mm) in diameter any part of which is within 1,500 microns of the center of the macula. These patients are at high risk for decreased central acuity due to macular edema.[4]

Preproliferative Diabetic Retinopathy

Patients with background diabetic retinopathy and evidence of more extensive retinal nonperfusion are said to have preproliferative diabetic retinopathy. Fundus findings in these patients may include venous beading (irregular areas of venous narrowing), large blot retinal hemorrhages, cotton wool spots, and intraretinal microvascular abnormalities (which consist of dilated capillaries and areas of neovascularization that have not left the confines of the retina). Proliferative diabetic retinopathy develops in 10% to 40% of patients with preproliferative diabetic retinopathy after one year of follow up.[5-7]

Proliferative Diabetic Retinopathy

In proliferative diabetic retinopathy new blood ves-



Figure 1.—In this case of background diabetic retinopathy with marked diabetic macular edema a ring of lipoprotein exudates is seen in the macula. Focal photocoagulation treatment in this patient improved visual acuity from 20/40 to 20/20.

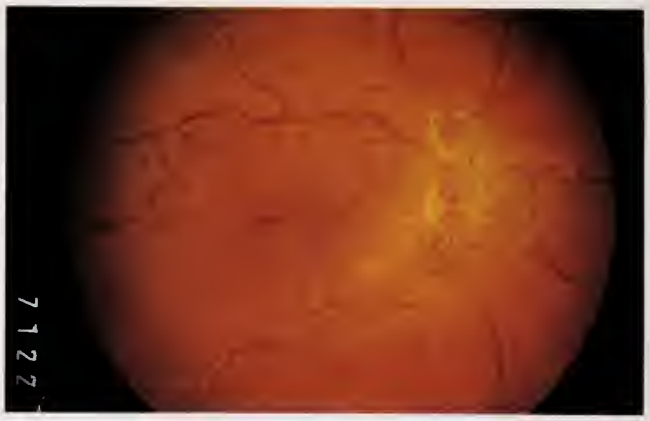
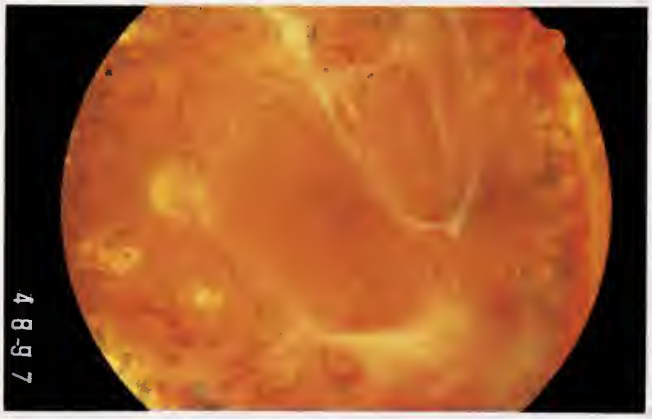


Figure 2.—Florid disc neovascularization in this patient was a clear indication for pan retinal laser photocoagulation. While the risk of blindness would be 26%, at 2 years without treatment, with treatment the patient was able to maintain useful vision.

[The cost of color reproduction is borne by the authors.]



Fiqure 3.—Failure to receive early pan retinal photocoaqulation for high risk prolifertive diabetic retinopathy may lead to traction and ischemia of the macula as in this patient. Once these changes occur visual prognosis may be less favorable with ambulatory vision (better than 5/200) often the goal rather than reading vision (20/40 or better).

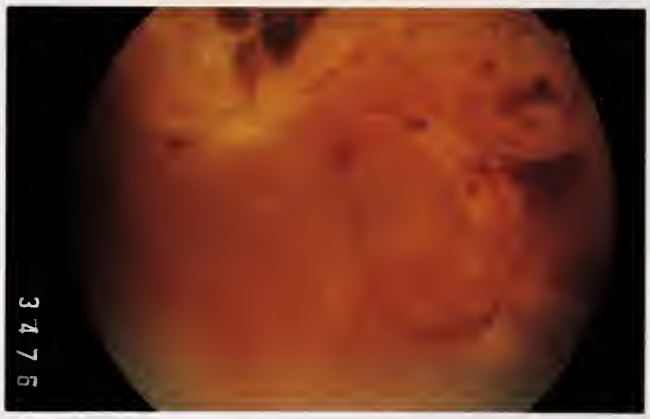


Figure 4.—High risk proliferative diabetic retinopathy may lead to traction retinal detachment as in this patient. Without treatment total, permanent blindness is inevitable. With surgery this patient recovered 20/40 vision.

sel growth occurs past the retinal surface into the vitreous cavity in response to broad areas of retinal nonperfusion (Figure 2). Secondary complications may result in visual loss in these eyes including dense vitreous hemorrhage from the fragile neovascular walls and traction retinal detachment from contraction of associated fibrovascular tissue (Figures 3 and 4). Eyes with neovascularization occupying more than 1/3 of the optic disc surface or with vitreous hemorrhage and neovascularization elsewhere in the fundus over 1/2 the size of the optic disc are said to have high-risk proliferative retinopathy. Patients with high risk proliferative retinopathy have a risk of permanent, severe visual loss (to levels insufficient to allow ambulation) of over 25% within 2 years if not treated.[8]

The natural history of untreated proliferative diabetic retinopathy leads to blindness in approximately half of patients.[9,10]

Hypertension and Diabetic Retinopathy

The retina capillary closure that occurs in all eyes with diabetic retinopathy may decrease central visual acuity when the macular circulation is involved. This has anecdotally been described as more common in patients with both diabetes mellitus and systemic hypertension; a number of studies have shown an

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association between diastolic hypertension and progression of diabetic retinopathy.[11]

American Academy of Ophthalmology Recommendations

Dilated Examination

Careful dilated examination by an experienced observer is essential in the follow-up of patients at risk for diabetic retinopathy; when examination is performed without dilation staging of the presence and severity of diabetic retinopathy is typically incorrect in 50% of cases.[12,13]

Initial Examination

The prevalence of diabetic retinopathy is directly related to the duration of diabetes. In patients with juvenile onset disease the exact time of disease onset is usually known; in patients with adult onset disease the exact time of disease onset is often not known. These facts are reflected in the American Academy of Ophthalmology recommendations for the timing of initial examination. In patients 30 years or younger at the time of diagnosis initial eye examination is recommended 5 years following onset of diabetes; in patients 31 years or older at diagnosis initial examination is recommended at the time of diagnosis. Both groups of patients should have routine yearly follow up examination; patients with findings of diabetic retinopathy may require more frequent follow up depending upon their abnormalities.[14] The rate of diabetic retinopathy development at one year is 5% to 10% in those patients with no retinopathy at initial examination.[5,6]

The pregnant diabetic is at increased risk for advancement of diabetic retinopathy and should undergo initial examination during the first trimester; routine follow-up is recommended 3 months later with earlier follow-up in those patients with abnormal findings.

Laser Photocoagulation for Diabetic Macular Edema

Laser photocoagulation is recommended for most patients with clinically significant diabetic macular edema. Definitive diagnosis of clinically significant diabetic macular edema requires careful examination at the slit lamp using a contact lens designed for high-detail stereoscopic fundus examination and fundus fluorescein angiography is recommended prior to laser photocoagulation. This type of photocoagulation is called focal photocoagulation when applied only to leaking microaneurysms and grid photocoagulation when applied to areas of diffuse leakage. Focal photocoagulation spots are relatively light and are applied with the goal of closing off leaking microaneurysms or other areas of leakage.

While little hard evidence exists, there are theoretical reasons that suggest appropriate treatment by the primary care physician of systemic hypertension, proteinuria, and hyperlipidemia may help the resolution of diabetic macular edema in these patients.

Laser Photocoagulation for Proliferative Diabetic Retinopathy

Pan retinal photocoagulation in which the majority of the retina surrounding the macula and optic disc is treated with heavy burns destroys marginally perfused areas of retina presumed to be responsible for the production of peptide growth factors underlying the process of neovascularization. Prompt treatment is important once high-risk proliferative diabetic retinopathy develops as the vascular but not the fibrous component of proliferation will usually regress following treatment.[10] While the Diabetic Retinopathy Study (DRS) noted a 57% reduction in severe visual loss in patients with high-risk diabetic retinopathy treated with pan retinal photocoagulation, Ferris has noted that current treatment of proliferative disease yields a treatment response more on the order of 90%. Only 5% of treated patients with proliferative disease became legally blind after 5 years of follow-up in the recent Early Treatment Diabetic Retinopathy Study; data from the DRS suggests that, untreated, approximately 50% of these patients would have become legally blind within 5 years.[9]

Metabolic Control

The tightness of glycemic control has been speculated as one factor in the development of diabetic retinopathy but only recently has evidence emerged to support tight metabolic control. The Diabetes Control and Complications Trial found a 60% reduction in the rate of diabetic retinopathy development over an average follow up of 7 years in patients under tight control as compared to patients under conventional control in whom the goal was a feeling of clinical well-being. In addition to the 60% reduction in the rate of diabetic retinopathy development patients in the tight control group also experienced a 60% reduction in the rate of development of nephropathy and peripheral neuropathy. This study, while detailed results have still not been published, gives the first

firm evidence that diabetic retinopathy cannot only be treated but also, to some degree, prevented.[15] Another recent study has suggested that systematic hypertension may also play a role in the onset of diabetic retinopathy, addinq further evidence of the importance of treatment of the entire patient in the prevention of diabetic complications.[16]

Summary

Identification, treatment and even prevention of diabetic retinopathy is a vision-saving process that is effective only through the collaboration of the primary care physician and the ophthalmologist. Due to misconceptions and lack of knowledge in the general population, ophthalmic examination of patients with diabetic retinopathy often is not performed without the intervention of the patient's primary care physician. Visual loss from diabetic retinopathy is largely preventable; because advanced diabetic retinopathy may develop without visual symptoms, strict adherence to the American Academy of Ophthalmology recommendations (initial examinations within 5 years of diagnosis in patients under 30 years and at the time of diagnosis in patients over 30) is vital.

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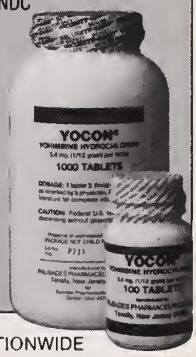
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Selective Lymphadenectomy In Early Stage Melanoma

Using Gamma Guided Surgery to Identify Sentinel Nodes

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*Bill V. Hewett, M.D.**
Joseph B. Logic, M.D.†
Daryl Strachner, B.S.

Every physician in Alabama who sees skin disorders is aware that cutaneous melanoma is increasing at an alarming rate. The incidence of this malignancy continues to rise faster than that of any other cancer.[1] Despite increased awareness of melanoma by both patient and physician that has led to earlier detection and treatment the death rate from cutaneous melanoma has doubled over the last 35 years.[2] Data from the National Cancer Institute show the mortality from this malignancy in white men and women in Alabama to be among the highest in the U.S.[3] Treatment of cutaneous melanoma should be of more than passing interest to most practitioners in this state.

Over the last 20 years surgeons who treat cutaneous melanoma have became increasingly aware of the quality of life of patients undergoing therapy. In view of this concern the amount of tissue removed with the primary lesion today is much smaller, and large, disfiguring resections including amputations are rarely encountered.[4] Elective removal of clinically uninvolved nodes (prophylactic lymphadenectamy) that may result in significant morbidity has also been reevaluated.[5]

The concern over elective lymphadenectamy applies only to early stage (Stage I-II) disease in which regional lymph nodes clinically are not involved and the primary lesion is ≤ lmm in depth. There is almost complete agreement that thin melanomas do not require prophylactic removal of lymph nodes because there is little possibility for nodal metastasis.[5]

The need for elective lymphadenectomy in treating Stage I-II melanoma remains controversial, because the results of many retrospective analyses and several prospective trials comparing prophylactic lymphadenectomy to therapeutic lymphadenectomy are contradictory.[6] To prevent unneeded removal of lymph nodes, Ross[7] states that by limiting lymphadenectomy only to those harboring microscopic nodal disease, surgery and its sequela would then be applied only to patients most likely to benefit from it. The problem has been to identify patients who harbor subclinical metastasis in regional nodes.

In an attempt to solve this problem Morton and coworkers[8] at UCLA in 1990 described a way to identify lymph nodes within the regional node basin as the likely site of early microscopic spread of melanoma. These "sentinel nodes" were identified by mapping lymphatic drainage using vital blue dye injected around the primary site. Blue stained lymph nodes considered the lowest in the nodal chain and closest to the primary site were removed and examuned separately before a regional lymphadenectomy was done. One to three sentinel nodes were identified in 80% of over 200 specimens. A total of 40 sentinel nodes (20.6%) was found to contain micrometastatic melanoma detected by either H&E or immunohistochemical staining. Skip metastasis in which tumor bypassed the sentinel nodes was found in only 1% of specimens. Morton concluded that by limiting lymphadenectomy to those with positive sentinel nodes 80% of early-stage melanoma patients could be spared the expense and morbidity of prophylactic

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lymph node removal. Subsequent experience at MD Anderson Cancer Center and University of South Florida has confirmed that sentinel node identification is possible in at least 80% of patients.[7]

Although Morton[9] noted there is a steep learning curve associated with his procedure he stressed that "substantial experience is required to develop the technical skill to achieve a high success rate..." What is not stressed is that identification of lymphatic channels leading to the sentinel node requires elevating skin flaps that can cause problems with seroma formation, necrosis of wound edges, and wound infection.[9]

Because of the extensive experience needed to achieve a success rate of only 80% we looked for another means of identifying sentinel nodes that could make the procedure both easier and more accurate. Radiocolloids injected intradermally are known to be transported via cutaneous lymphatics to regional nodes, and cutaneous lymphoscintigraphy has been used to identify ambiguous lymph drainage in head and neck and axial melanomas.[10] It seemed that a radiopharmaceutical could be substituted for dye and a commercially available probe to detect radiation could be used to identify radiolabeled sentinel nodes.

MATERIAL AND METHOD

Technetium-99 labeled sulfur-colloid is a pure gamma ray emitting radiopharmaceutical widely used for diagnostic imaging of liver, spleen and bone marrow. With a half life of 6 hours it is effective during the examination time but avoids problems with prolonged contamination. The size of the sulfur-colloid particles (100nm-2,um) usually prevents the agent from passing beyond the first lymph node encountered. A commercially available gamma ray detection probe (C-Trak, Care-Wise Medical Products Corp., Morgan Hill, CA) is a portable, battery-operated scintillation probe that monitors gamma ray counts, converts them to both audible and visual signals, and records them on a printout. A collimator narrows the field of view to minimize background radiation.[11]

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CONCLUSION

Sentinel node identification and examination appears very promising as a means of determining which early-stage melanoma patients harbor nodal micrometastasis and are most likely to benefit from prophylactic lymphadenectomy. Our experience, although limited, leads us to believe that a technique that uses radiolabeling is preferable to that which uses vital dye to identify sentinel nodes. Radiolabeling is user friendly and requires little experience to become proficient in its application. Since there is no need to trace dye stained lymphatics there is no need to create skin flaps with their possible complications. Radiocolloid unlike vital dye is usually arrested at the first lymph node, making it less likely that proximal nodes will be mistaken for sentinel nodes. Increased experience with immunohistochemical techniques will allow more rapid identification of metastatic disease and enable lymphadenectomy to be done at the time of positive sentinel node biopsy. If the future submicroscopic metastasis may be confirmed by means of lymph node culture[12] that will make sentinel node identification more sensitive and melanoma staging more accurate.

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A GREAT WAY TO SERVE

Preserve the Inner Space

As the cottage industry of private practice medicine is buffeted by the storms of change, new physicians in the class of '93 are exhorted to protect the inner space of the doctor-patient relationship whatever transpires.

*By Professor William W. Winternitz, M.D.**

Dean Ficken, Dean Boyce, Dr. Tietze & Dr. Hopkins, members of the class of '93, spouses, parents, friends and honored guests: I am most pleased and honored to have been invited to address you at this time, a moment of signal importance as you move from the role of students to that of responsible physicians. Your transition has been long and gradual, but the MD degree indicates that society now recognizes your status. You are officially accorded the awesome rights, privileges, duties and responsibilities that go with this title.

This is the 17th annual honors convocation of our program. CCHS has grown and matured these past two decades. But today, it is appropriate that you be more interested in the future than in the past.

This is an era of change—economic, political, social and moral. You will enter the profession as pioneers, developers, and experimental subjects! You will participate in the new organization of medicine, and you will have a unique opportunity to help shape the future and ensure progress in medical care.

Not much is definite about medicine in the coming years. We have been bombarded with talk of health care reform, a "crisis" long in the making but now nearing a crest. Change is certain; its shape is uncertain.

You know about our enormous cost of health care, increasing by as much as 10% per year, $80 billion this year. Yet more than 30 million Americans are uninsured, and outcomes are no better than in countries that spend significantly less.

Economist Paul Starr states that while the uninsured ("they") have held our concern, now the economic impact of health care is so great that "they" have become "us." Therefore, there is general agreement that something must be done. This is the economic and political engine driving reform.[1]

From a different viewpoint, where you have been, care is not available to the poor other than Medicaid for the destitute. The working poor—uninsured—may be forced to choose between food, shelter and medical care. Unable to work because of illness, they may lose everything and accumulate enormous debts.

Many minds are now grappling with this problem, including Hillary Rodham Clinton and her task force.

The cost of medical care must stabilize, at least at inflation levels. But how do you save money while expanding basic care to cover all Americans at a time when our population is aging and will have increasing needs?!

Perhaps it would help if all of us were more like Dr. Roseanne Cook, the Catholic nun practicing in Pineapple, Alabama. Although her income and budget: are probably modest, she stated her job satisfaction is 200%. This says something about the rewards of primary care.

As physicians and citizens, you can have input in the development of new systems. As primary care physicians, uniquely informed about your patients' needs, you can be pivotal for the successful function of these systems. Primary care is finally being recognized for what it is: the basic foundation of medicine.

Future possibilities include "single payer" systems (as in Canada), restricted medical groups (IPA, PMD, HMOs), "managed competition" or mixtures of the above. They may include "private care" for those who wish it and are able to pay more. Unlike the present time, the poor (including the working poor) may have equal access to basic care—an improvement.

Your practice environment will be different: political and economic forces will be intense. The cottage industry of private practice will be modernized. You will be involved as leaders, followers, or possibly as victims. As the Chinese philosopher said, "You live in interesting times."

You have probably heard some physicians say that, today, they would not advise a daughter or son to go into medicine: "too much interference/paperwork/red tape...," "not fun anymore," etc. I believe you will

*Given at the 17th annual Honors Convocation, College of Community Health Sciences, University of Alabama School of Medicine, Tuscaloosa program, May 22, 1993.

not find this to be true. The basic unit, the doctor-patient relationship, will continue to be central to your future practice.

Dr. Edmund Pellegrino has described medicine as "the most humane of the sciences, and the most scientific of the humanities."[2] Your science must be solid and up to date—not easy to do. But when applied to the human dilemmas you confront, bio-science must be tempered. Psychology, sociology, economics, and humane concern must be brought into your interactions with the people who come to you for help. This is a challenge and privilege few professions can match. To so serve society is a reward in itself.

The present turmoil concerning health care is important, but it need not, should not, invade the inner space of the doctor-patient relationship.

Morals

In addition to economic and political change, you are on shifting moral grounds. You are no longer supported by universal values, and orthodox principles may not hold. This is an era of questioning and moral relativism. Dr. Pellegrino gives examples of drastic shifts in moral theory in the suggested acceptance of physician-assisted suicide, voluntary and even non-voluntary euthanasia, health-care rationing, buying and selling organs, renting uteri, etc.[3]

The four ancient principles of medicine may not suffice: do good, do no harm, patient autonomy, and justice (access to care). They are no longer adequate to serve as the moral foundation of your practice.

How will you rationalize your position on intractable issues like euthanasia, abortion and clinical decisions that are economically based? Directly or indirectly, you will participate in the development of a new philosophical base, a new version of medical ethics.

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bers, 13 will enter primary care residency; 7 of you have elected family medicine; and 5 have chosen to remain here at CCHS. There is no surer sign of success than the approval and commitment of our own graduates.

Predictions

Predictions are difficult, and with this in mind, allow me to look into my crystal ball:

Prediction #1: Most of you will practice medicine at the forefront, and you will be busy, appreciated, and professionally fulfilled.

Prediction #2: As a group, you will continue the traditional role of doctor/teacher for the benefit of students, residents and colleagues when you have the opportunity.

Prediction #3: Your incomes will be more than adequate, but most of you will be "comfortable" rather than "wealthy." You will not miss the extra cash! (My sense has been that income is not your major motivation.)

Prediction #4: Health care reform will evolve amongst much debate over five to ten years. Costs will be more controlled, and access to basic care will be open to most Americans. Controls will be present, but they may be no more onerous than now.

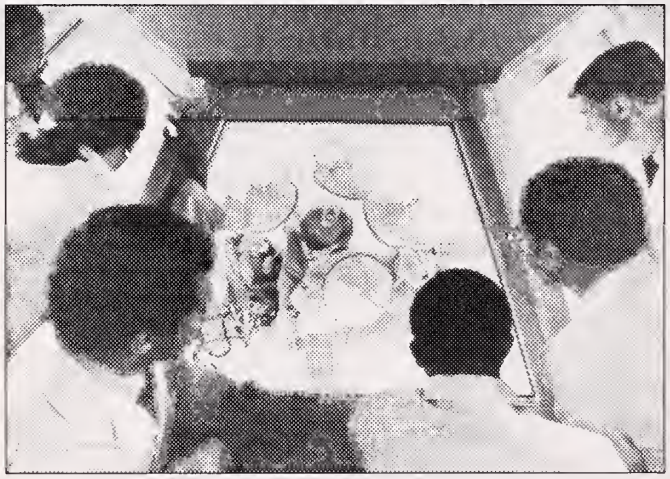
You will be active citizens in your community. However, while our new health care delivery system is made workable, you may find yourself at odds politically with your colleagues and fellow citizens. As young doctors, many of you will be on the firing line, but [more significantly] you enter your profession at a time that will allow you to exert significant [profound] leadership.

Thank you for the opportunity to speak to you today. I join all the faculty in wishing you well.

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Henry Gray of Legendary Textbook Fame

*Martin Duke, M.D.**
Reprinted from Connecticut Medicine, 7/93

What is known about Henry Gray, author of *Anatomy, Descriptive and Surgical*,[1] a textbook published in 1858 that has since become better known as *Gray's Anatomy*? Who was this physician and anatomist whose name is remembered almost solely for this unique publication? Since most medical books have a limited life-span and "like human beings, seldom live for a hundred years,"[2] it is extraordinary that a text on anatomy, which appeared in its 30th American edition in 1985[3] and 37th English edition in 1989,[4] has not only remained a staple in medical education for over 130 years but has continued to enjoy widespread popularity. This remarkable longevity is similar to and should be compared with that of another equally significant and well-known medical landmark, *The Principles and Practice of Medicine* by William Osler.[5]

Sparse accounts of Henry Gray' s life, career, and family background are contained in obituary notices written at the time of his death[6,7] and in three later articles, all very similar in biographical content, published prior to 1959.[8,9,10] Further details have since become available from correspondence in 1960 between Frederick Laurence Gray, Henry's grandnephew, and Lea & Febiger, publisher of American editions of the famous anatomy text (Letters from the archives of Lea & Febiger. Unpublished material), and from a genealogic survey of the Gray family currently in progress (Nicol KE. Personal communication). From these and other sources, a biographical account will be provided of this 19th-century English physician, the author of an anatomy tour de force that has long played a formidable role in the rites of passage for many during their medical training.

Family Background

Public documents indicate that Thomas Gray, also referred to as William or William Thomas Gray, was appointed messenger in ordinary to two English monarchs, George IV in 1821 and William IV in 1830. He resided in London at No. 8 Wilton Street, Belgrave Square, with his wife, the former Ann Walker, bequeathing the home and its contents to her when he died in 1838 (Nicol KE. Personal communication). The couple at that time had four children: Henry, the subject of this article, a physician and anatomist, and the author of the famous and durable anatomy textbook referred to earlier; Thomas William, a member of the legal profession, an Attorney of Her Majesty's Court of Queen's Bench, a Solicitor in Her Majesty's High Court of Chancery, the father of 10 children, and the grandfather of the aforementioned Frederick Laurence Gray; Marian, an unmarried daughter who died at a young age; and Robert, who trained to be a naval surgeon but was lost at sea in his 22nd year (Letters from the archives of Lea & Febiger. Unpublished material) .

Medical Career

Henry Gray lived throughout his life at the family home on Wilton Street, a fact commemorated by a memorial tablet, the familiar blue plaque, affixed to the house. No original documents have so far been located verifying the date of Gray's birth, although reasoning from his age of 34 years and the year he died in 1861 as officially recorded on a death certificate at the General Register Office in London, it is, until further evidence appears, presumed to have been in 1827. There is no information available about his early years.

In 1845, Gray enrolled at St. George's Hospital Medical School where his signature appears in the Pupil's Register. That same year he was the recipient of a botanical prize (Nicol KE. Personal communication). Gray thereafter maintained an association with the above institution for the remainder of his brief medical career, serving at various times from 1850 until his death in 1861 as house surgeon. Lecturer of Anatomy, Demonstrator of Anatomy, curator of the St. George's Hospital Museum, and surgeon to the St. George s and St. James's Dispensary. He was a

*Martin Duke, M.D., Cardiovascular Diseases, Internal Medicine, Manchester Memorial Hospital, Manchester, the University of Connecticut Health Center, Farmington, and the Editorial Board of Connecticut Medicine.

Letters from the archives of Lea & Febiger, founded in 1785.

Member of the Royal College of Surgeons, 1848, a Fellow of the Royal Society, 1852, a Fellow of the Royal College of Surgeons, 1860, and belonged for many years to both the Pathological Society and the Royal Medical Chirurgical Society[8,10,11] (Nicol KE. Personal communication).

Medical Publications

In 1848, Gray distinguished himself with a prize-winning though unpublished essay "On the anatomy and physiology of the nerves of the human eye," a copy of which, as noted in a later publication, was placed in the library of the Royal College of Surgeons.[12] Between 1850 and 1858, he published four articles and two books, an impressive literary output during a short span of years. The earliest of these works, "On the development of the retina and optic nerve, and of the membranous labyrinth and auditory nerve,"[12] was communicated to the Royal Society in 1850 by the well known William Bowman (1816-92), Professor of Physiology and of General and Morbid Anatomy in King's College, London, and an eminent ophthalmic surgeon and renal physiologist.

Writing in an article entitled "On the development of the ductless glands in the chick," Gray made the original observation that "the spleen is developed from the surface of a fold of the 'intestinal lamina', in the form of a small oval-shaped mass of blastema, quite independent either of the pancreas or stomach."[13] Further research, aided by funds given by Parliament to the Royal Society for the promotion of science, resulted in a dissertation, *The Structure and Use of the Spleen*, for which Gray received the Astley Cooper Prize in 1853. This work was published the following year by John W. Parker and Son as a volume of 380 pages and 65 woodcuts.[14]

In describing a dermoid cyst of the ovary,[15] Gray observed that part of the "contents of this cyst consisted of a softish, white substance, the surface of which was perfectly smooth, and presented all the characters [sic] of brain. On microscopic examination it was found to consist entirely of the ordinary elements of nervous matter." This case was presented, he added, "as it may assist, to a certain extent at some future period, in explaining the law which governs the development of these remarkable tumours."[15]

A lengthy article, "On myeloid and myelo-cystic tumours of the bone; their structure, pathology, and mode of diagnosis," outlined the difficulties in distinguishing between benign and malignant bone tumors:[16]

[T]here are a class of tumours which have their origin either upon, or in the interior of, the bones, and which bear so close a resemblance to malignant disease, that the eye fails to detect their true character. Minute examination of them, however, shows them to consist,—partly, of structures in every respect identical with some of the normal constituents of the medulla—partly, of a fibrous element mixed up with cysts of varying numbers and size—and, occasionally, of fibro-cystic structure, or some of the primordial elements of bone itself.

It would thus appear, that nonmalignant tumours of bone may consist of structures which are composed entirely of a tissue analogous to one of the normal elements of bone, or of some, or all, of these tissues intermingled.[16]

Other observations by Gray in this paper—the long duration of the disease, its nonrecurrence, its confinement to osseous tissue, its slow growth—supported his contention for the "innocent character" of some of these tumors.[16]

Gray's Anatomy Text

What proved to be the most notable achievement of Gray's career, although this was obviously not apparent as such until many years later, occurred in 1858 with the publication of the first English edition of his now famous textbook "*Anatomy, Descriptive and Surgical*"[1] (Fig. 1), the initial American edition of which appeared the following year. In the opening words of the preface, Gray recorded his purpose for writing this book:

This work is intended to furnish the Student and Practitioner with an accurate view of the Anatomy of the Human Body, and more especially the application of this science to Practical Surgery.

One of the chief objects of the Author has been, to induce the Student to apply his anatomical knowledge to the more practical points in Surgery, by introducing, in small type, under each subdivision of the work, such observations as shew the necessity of an accurate knowledge of the part under examination.[1]

A book review in *The Lancet* described the first edition as having 782 pages and 363 large woodcuts, the latter prepared from original drawings by Gray's friend and associate Henry Vandyke Carter (1831-97), Professor of Anatomy in Queen's College, Bombay, and late Demonstrator of Anatomy at St. George's Hospital.[17] Comments in this review were prophetic:

As a full, systematic, and advanced treatise on anatomy, combining the various merits of the volumes of many countries, scientifically excellent, and adapted to all the wants of the student, we are not acquainted with any work in any language which can take equal rank with the one before us.[17]

Another reviewer[18] commended the work for the "teaching power" of its visual presentations and, foreshadowing its future success, concluded that this is "a book which must take its place as *the* manual of *Anatomy, Descriptive and Surgical*" (the italics are those of the original reviewer).

A limited and not too revealing glimpse into Gray's professional life while work was in progress on the book may be found in the journals of his colleague, Dr. H.V. Carter, at the Wellcome Institute for the History of Medicine (Nicol KE. Personal communication).

Gray's Death

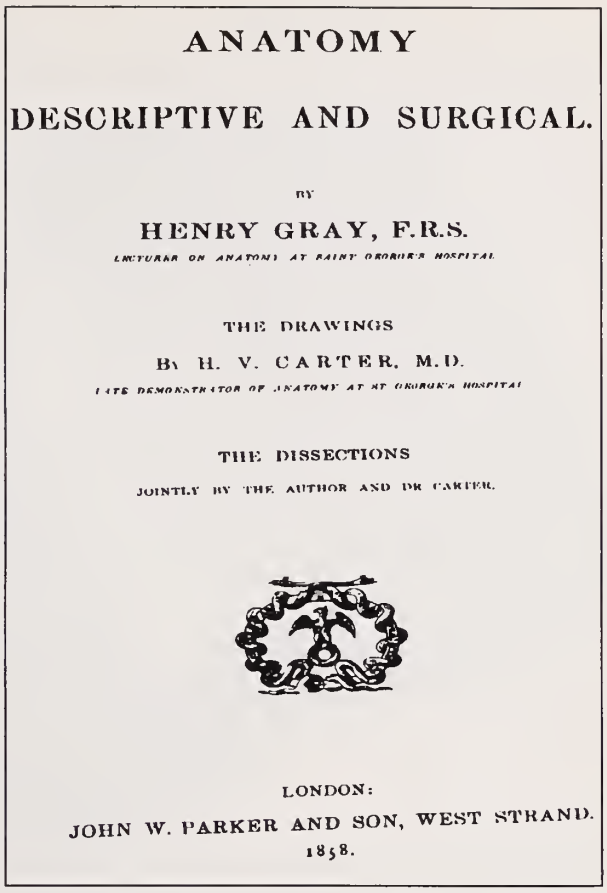
While attending a nephew for smallpox, Gray became fatally ill with the disease.[8,9] His death certificate, referred to earlier, recorded that he died from "confluent smallpox" on June 12th, 1861, at the young age of 34 years.

Noted on the certificate was the interesting comment that he had been vaccinated in childhood. The age of 34 years was also inscribed on Gray's tombstone at Highgate Cemetery in London, although death was indicated to have been on June 13th, a day later. Strangely enough, the burial register for Highgate Cemetery, notwithstanding the inscription on the tombstone, stated his age as 35 years (Nicol KE. Personal communication), while obituary notices reported that he was 36 years old when he died.[6,7] Whether there was a mysterious reason for these inconsistencies, or whether they were merely the result of human error and carelessness, may never be clear and can only be speculated upon.

Gray, a bachelor, was engaged at the time of his death to a Miss Winter (Letters from the archives of Lea & Febiger. Unpublished material). No further documents have been located that provide other details about his personal life. Ann Gray, his mother, died in 1866 at the age of 74, five years following her son's death, and was interred at the same gravesite. Known relatives of Henry Gray alive today are descendants of his brother Thomas William (Nicol KE. Personal communication).

Founder of an Institution

Since they were first published in the 19th-century, both the American and English versions of Gray's anatomy textbook have been frequently and skillfully revised by many well known editors. With all the changes and additions that have occurred, Gray's actual contributions would probably be difficult to find in current editions of this work.[3,4] It may be appropriate, therefore, when establishing his place in medical history, to consider this excerpt from an article by the medical historian F.N.L. Poynter: "He [Gray] was once the author of a book, but he might more truly be regarded as the founder of an institution."[19]


ANATOMY

DESCRIPTIVE AND SURGICAL.

BY

HENRY GRAY, F.R.S.

LECTURER ON ANATOMY AT SAINT GEORGE'S HOSPITAL

THE DRAWINGS

BY H. V. CARTER, M.D.

LATE DEMONSTRATOR OF ANATOMY AT ST GEORGE'S HOSPITAL

THE DISSECTIONS

JOINTLY BY THE AUTHOR AND DR CARTER.

LONDON:

JOHN W. PARKER AND SON, WEST STRAND.

1858.

Figure 1.—Title page of the first English edition of Henry Gray's *Anatomy, Descriptive and Surgical*, published in 1858. (Courtesy of Harvey Cushing/John Hay Whitney Medical Library, Yale University, New Haven.)

Acknowledgments

The author thanks Mr. Keith E. Nicol of London, England, for providing information from a genealogic survey of the Gray family that he is currently undertaking, and Lea & Febiger, publishers, founded in 1785, for making available from their archives unpublished letters written to them by Frederick Laurence Gray.

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Friends, Romans and Countrymen

President Arthur L. Eberly Jr., MD
Journal of the Florida Medical Association

Life is about trade-offs, compromise. If you doubt this, then cogitate: Who among us does not compromise when crossing the street in busy traffic? Certainly there are some principles on which we cannot and will not compromise. Certainly there comes a time to "draw a line in the sand."

Those physicians who are active in their county societies compromise part of their income to participate in their own governance. More than that, they compromise part of their time which could be spent with family or at leisure. Should these same physicians choose to participate at the FMA level or even AMA, there goes more "quality time" and/or loss of income.

Remember time is one resource we can never replenish!

Why these comments about compromise from a President two months in office at the time of this writing?

I address the subject because too often we hear the FMA or AMA "didn't stick by their guns," or "wimped out on their principles" or "let down" this specialty or that specialty, all because of a compromise (trade-off) with another organization (Florida Bar, Florida Hospital Association, etc.) or in the Legislature. Usually this compromise involves a position or bill in the Legislature we could not carry without the help of others, hence the compromise. I want to remind you that the FMA/AMA represents all of medicine, all of our patients, and all doctors. Having said that, it becomes obvious that if we represent this large a constituency, then there must be broad issues we support which will make everyone happy. There will be narrow issues we must address where the position we take as an organization will aggravate many and inflame a few.

I want you as members, whether officers in your county societies or members of the rank and file, to realize your Board of Governors and Executive Committee usually take positions on issues already dictated by the House of Delegates. If we must make decisions that the House has not addressed, we reach them after fair debate, usually with input from county society executives and officers, plus similar input from the specialty societies.

You should be aware of the makeup of the Executive Committee and the Board of Governors. On the Executive Committee are two F.P.s, four internists, two surgeons, and one radiologist. On the Board of Governors in addition to these nine physicians, are five F.P.s, one internist, four surgeons, two pathologists, one pediatrician, president of the Alliance (formerly Auxiliary), a young physician surgeon, resident physician (surgeon), and a medical student.*

Were you to identify the city of origin of these members of the Board of Governors, you would find that the geographical distribution is throughout the state.

I think most persons of goodwill will agree that their representation is a fair one, demographically as well as specialty-wise. The Board meetings are far from "cut and dried" and much debate is engendered on many issues.

My plea is for understanding, trust, support and prayers for your officers and staff during the coming months. We have a way to travel and much to do. Much of our success this year depends upon cooperation between county societies and the FMA and specialty societies and the FMA. Should we have areas of disagreement, we must communicate with one another and try to resolve conflict. Absent conflict resolution, we must agree to support one another in our areas of mutual agreement!

Thank you for your support thus far. I pledge my efforts and cooperation toward the goals of the FMA and toward better understanding between the FMA family and its constituencies.

Thanks also to those of you who have written in response to my inaugural address, especially the poem "The Man in the Glass" (June 1993). Remember, compromise is not necessarily a four-letter word.

*Subspecialties excluded



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The state of Alabama contributed $47,102.88 to the AMA-ERF this year. This included over $42,000 raised by the auxiliaries across the state, plus physicians' contributions of almost $5,000.

The county and state auxiliaries raise funds for AMA-ERF through various auctions and raffles, selling stationary, Holiday Sharing Cards, as well as accepting donations for memorials and honorariums. Every dollar contributed to the foundation goes to the medical school designated. No portion of the contribution is used for administrative costs.

Several different funds have been established by AMA-ERF to support the diverse needs of medical schools. The Medical School Excellence Fund provides grants to medical schools to use where they are most needed. These unrestricted funds support special student programs, research projects, guest lectures, and attendance at conferences and meetings, as well as subsidize costs for new equipment, books and other publications, and building improvements. The oldest and largest of the funds, the Medical School Excellence Fund, has provided more that $48 million to medical schools since 1957.

The Medical Student Assistance Fund provides monies for medical schools to use in direct financial aid for students. Begun in 1983, this fund provides an average of $500,000 for student loans, grants, and scholarships each year. The specific programs vary from school to school; the only requirement is that the school use the funds to help support bona fide educational expenses for medical students who are in need.

Contribution to AMA-ERF can be given to the fund and school of your choice. Contributions to the Medical School Excellence Fund can be designated for an alma mater or a school in your community. Contributions for the Medical Student Assistance Fund can also be directed to specific medical schools, but not particular students.

The foundation has two additional funds. The Development Fund is used at the discretion of the foundation's board of directors to support pilot and experimental health and medical programs, while the Categorical Fund provides monies to specific research areas.

Taken together, these funds have helped to support the highest standards of medical education in the world, research as a career path for talented young medical students, and quality patient care based on education and research programs respected worldwide.

AMA-ERF President Palma Formica, M.D., emphasizes the importance of county, state, and national efforts on behalf of the foundation. "Funds are needed by medical schools now more than ever. Your commitment to medical education sets the stage for everyone to contribute," she says. According to Dr. Formica, the foundation is unique in that 100% of each contribution is given to the designated medical school; no funds are deducted for administrative costs.

With spiraling costs and shrinking sources of funding, the nation's medical schools increasingly depend on private sources to help meet the educational needs of the country's future physicians. The AMA-ERF is such a source.

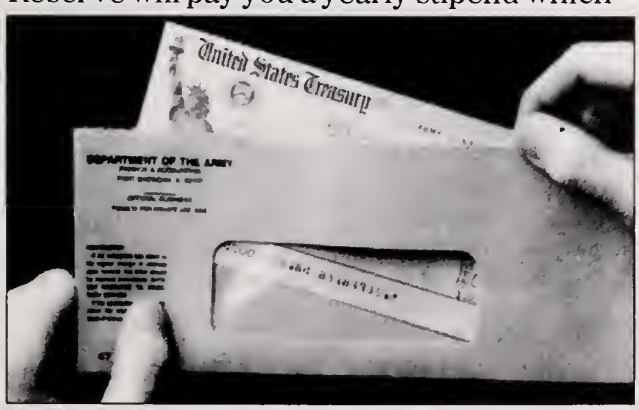
Donations to AMA-ERF are more than just charitable contributions; they are a legacy from one generation of medical professionals to another. The quality of medical care and of its practitioners depends on our continued support of medical schools nationwide through gifts to the foundation. Raising funds for AMA-ERF is our only national philanthropic endeavor.

The theme for the 1993-94 fund-raising year is "One Choice—One Hour". We are asking each physician and auxiliary member to contribute at least one hour of medical education this year. "One Choice ... One Hour" means that by contributing $21.03 to AMA-ERF, each member buys one hour of medical education for one medical student. It means that the tradition of excellence demonstrated during the 40-year history of AMA-ERF will again have real importance at the most practical level.

Please support the AMA-ERF this year. You may donate through your local Medical Auxiliary or directly to the State AMA-ERF Chairman: Joy C. Murphy, 3625 Longview Lane, Mobile, Alabama 36608.

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Call for Papers

1994 International Conference on Physician Health
September 16-20, 1994. Ottawa, Ontario, Canada

"Stress: The Profession, the Family and You"

The 1994 International Conference on Physician Health, co-sponsored by the American Medical Association, the Federation of State Medical Boards, the Canadian Medical Association, and the Federation of Medical Licensing Authorities of Canada is scheduled for September 16-20, 1994, at the Ottawa Westin Hotel.

Ottawa is Canada's capital and offers many national museums, over 60 miles of bicycle paths, hiking in Gateneau park, squash courts and swimming at the hotel and golf nearby.

The conference will provide a forum for practitioners and researchers to present recent findings and innovative treatment and education programs in physician health. This conference will address a range of issues, such as AIDS, HIV, problems related to aging, mental illness, substance abuse and physical disabilities and limitations, including those caused by general medical conditions. Possible topics for presentation include: presentation and treatment of health problems among physicians, the impact of disorders on physicians' families and practices, medical-legal issues facing hospital administrations and licensing boards, and material on health promotion and disease prevention. *Abstracts which address issues related to these topics (i.e., prevention, diagnosis, treatment, rehabilitation), but not dealing specifically with physicians are also welcome.*

Three types of presentations regarding these physician health issues are invited:

- **Poster Presentations**
 Written presentations of data-based research, epidemiological research, or program descriptions.

- **Paper Sessions**
 Oral presentation of scientific, data-based findings relative to the topic of physician health.

 Abstracts for poster presentations and paper sessions should contain an introductory statement on the significance of subject matter. Description of methods, results, and conclusions should follow the introductory statement.

- **Workshops**
 Training or instructional presentations, designed to improve specific skills of persons who work in the area of physician health.

 Abstracts for workshops should contain information on the program's intended audience, goals, teaching strategies, and materials. Evaluation data should be summarized

Abstracts may not exceed 200 words. Any abstracts exceeding that length will be rejected. Abstracts should be typed, double spaced, and mailed (not faxed). Four copies of the abstract should be sent, along with one self-addressed, stamped envelope. All submissions must list the primary and secondary authors and their professional affiliations. Telephone number and address of primary author must also be included.

Submissions *must* be received by February 1, 1994.

Abstracts will be submitted for blind review. Abstracts will be judged on their applicability to the conference topic area and their scientific merit. The decisions of the blind reviewers will be communicated to the abstract's primary author by April 1, 1994.

All presenters are expected to register for the conference at the AMA member rate. We are unable to provide any financial support for presenters. Presenters will also be responsible for their own transportation and hotel expenses, as well as making all reservations for same.

Send all materials to:
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Physicians dedicated to the health of America

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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with prevastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly alavated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravestatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin*, antacids [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Hardenan gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General.**)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3 4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1 2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Leboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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Vol. 63, No. 5 November 1993

ALABAMA MEDICINE

JOURNAL OF THE MEDICAL ASSOCIATION
OF THE STATE OF ALABAMA

IRA MAGAZINER'S RAT MAZE

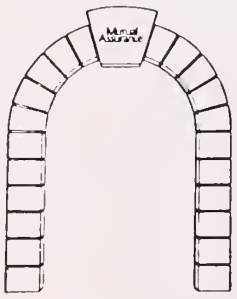


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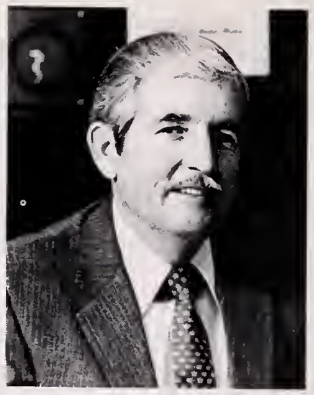
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About the Cover

{See Dr. West's Column, page 5.}

The flow chart on the cover, copyright 1993 by Ernst & Young, is the product of intensive work by experts in the international professional services firm. They studied Mr. Clinton's 1,400-page health care reform bill and converted it to this chart, which is repeated on page 4. Ernst & Young employs 64,000 people in more than 600 cities, including over 20,000 in 100 U.S. cities. The firm provides consulting services to hospitals, ambulatory care facilities, nursing homes, home health agencies, managed care organizations, physician group practices, and other health care organizations. Reprinted with permission.

EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Keynesianism Out of Control

"All progress is based upon the universal innate desire of every organism to live beyond its income."
— Samuel Butler, 1890

In this simplistic generalization, Mr. Butler laid claim to being the first Keynesian, even though John Maynard Keynes (1883-1946) was only 7 years old when this was written. It was Keynes, the English economist, who was generally credited with the federal deficit spending that characterized the New Deal under Roosevelt and most administrations since then. Even Richard Nixon once said, "We're all Keynesians now."

The Keynesian philosophy, greatly oversimplified, was that governments should spend ("invest") in times of slow economic growth to stimulate expansion but ease off in boom times. America got it only half-right — government spending in recent decades has not concerned itself with the underlying condition of the national economy. It just keeps rolling along, snowballing all the while, irrespective of expansion or recession. And that massive amendment to Keynes general theory has been made possible by our discovery of the beauties of mounting national debt. As a people, we have declared Samuel Butler's law to be just our cup of tea. We want it all and we don't want to pay for any of it.

Which brings me to Topic A, health care reform, specifically to Mr. Clinton's notions of refinancing one-seventh of the U.S. economy. He would do this by juggling megabucks all over the balance sheet, adding just a pinch of taxation on tobacco, and, like that, we would all have health security until death do us part. All we really need to accomplish his miracles of loaves and fishes is a nicely embossed plastic card. (In his stirring speeches, he held one up for all to see. That reminds me of the Air Force General on the lecture circuit in the 1950s, a time when the press was trumpeting the arrival of "push-button warfare" that would obviate the need for soldiers, pilots, etc. The General would refer to these and then announce that he would now show all that had been developed so far in this connection. He would open a box and pull out — you guessed it, a push button.)

To me, the Clinton card looks like the same charge cards that have already inundated Americans in a sea of consumer debt that parallels the national debt. And there is more than a casual connection between the two — as the federal government moved from a pay-as-we-go philosophy to one of putting everything on the cuff, so has the citizenry. In my own lifespan, debt has been magically transformed from a mortal sin to a marvelous panacea. And a huge new national debt is exactly where his plan would lead us, barring heavy taxation in one form or another, under one label or another.

As the autumn of high expectations and giddy hope yields to the winter of second thoughts and the spring and summer of hard-edged reality, I hope the Congress and the nation will finally see the potential calamity of Mr. Clinton's voodoo economics and insist on sane funding. People must be told that their wants must be supported by their money. But that will be the most difficult messages after generations of putting it on the cuff.

If, however, Congress goes along with any form of financing grounded on hocus-pocus number cooking, I fear for the future of my country. A vast new entitlement without tangible means of support could be a calamity beyond any other mistake in our history, taking down with it not only the finest health care system in the world but administering the *coupe de grace* to the national economy as well.

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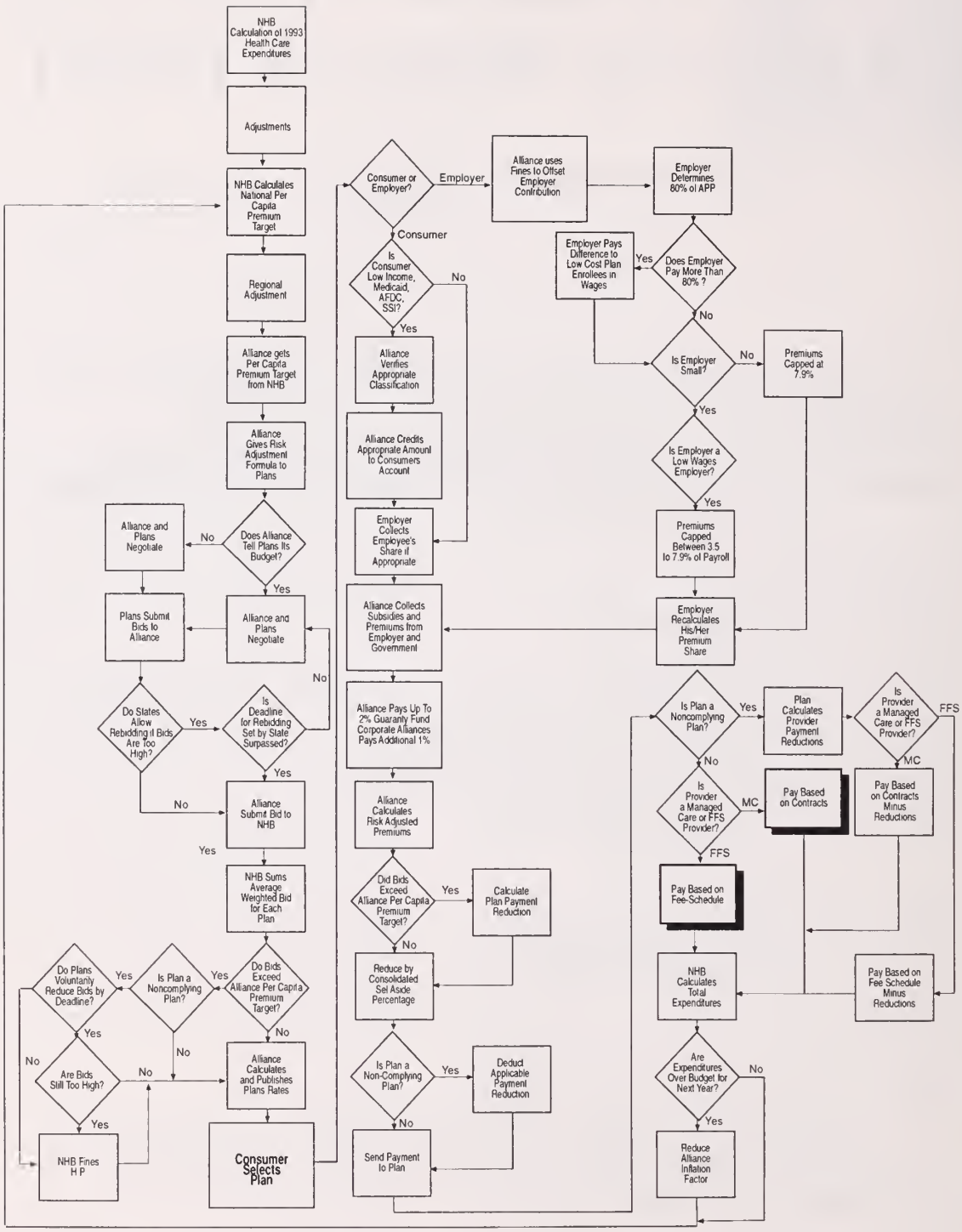
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Adjustments
NHB Calculates National Per Capita Premium Target
Regional Adjustment
Alliance gets Per Capita Premium Target from NHB
Alliance Gives Risk Adjustment Formula to Plans
Does Alliance Tell Plans Its Budget?
No
Alliance and Plans Negotiate
Yes
Alliance and Plans Negotiate
Plans Submit Bids to Alliance
Do States Allow Rebidding if Bids Are Too High?
Yes
Is Deadline for Rebidding Set by State Surpassed?
No
Yes
No
Alliance Submit Bid to NHB
Yes
NHB Sums Average Weighted Bid for Each Plan
Do Bids Exceed Alliance Per Capita Premium Target?
Yes
No
Is Plan a Noncomplying Plan?
Yes
No
Do Plans Voluntarily Reduce Bids by Deadline?
Yes
No
Are Bids Still Too High?
Yes
No
NHB Fines H P
Alliance Calculates and Publishes Plans Rates
Consumer Selects Plan
Consumer or Employer?
Employer
Alliance uses Fines to Offset Employer Contribution
Consumer
Is Consumer Low Income, Medicaid, AFDC, SSI?
No
Yes
Alliance Verifies Appropriate Classification
Alliance Credits Appropriate Amount to Consumers Account
Employer Collects Employee's Share if Appropriate
Alliance Collects Subsidies and Premiums from Employer and Government
Alliance Pays Up To 2% Guaranty Fund Corporate Alliances Pays Additional 1%
Alliance Calculates Risk Adjusted Premiums
Did Bids Exceed Alliance Per Capita Premium Target?
Yes
Calculate Plan Payment Reduction
No
Reduce by Consolidated Set Aside Percentage
Is Plan a Non-Complying Plan?
Yes
Deduct Applicable Payment Reduction
No
Send Payment to Plan
Employer Determines 80% of APP
Employer Pays Difference to Low Cost Plan Enrollees in Wages
Yes
Does Employer Pay More Than 80% ?
No
Is Employer Small?
No
Premiums Capped at 7.9%
Yes
Is Employer a Low Wages Employer?
Yes
Premiums Capped Between 3.5 to 7.9% of Payroll
Employer Recalculates His/Her Premium Share
Is Plan a Noncomplying Plan?
Yes
Plan Calculates Provider Payment Reductions
Is Provider a Managed Care or FFS Provider?
FFS
MC
Pay Based on Contracts Minus Reductions
No
Is Provider a Managed Care or FFS Provider?
MC
Pay Based on Contracts
FFS
Pay Based on Fee-Schedule
NHB Calculates Total Expenditures
Pay Based on Fee Schedule Minus Reductions
Are Expenditures Over Budget for Next Year?
No
Yes
Reduce Alliance Inflation Factor

PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

Ira Magaziner's Rat Maze

On the cover (and repeated on the page opposite) is a flow chart by the prominent national consulting firm of Ernst & Young of New York. Their experts pored over the President's ponderous 1,400-page health care reform proposal and plotted this graphic representation of what they call the "money flow."

A quick glance is almost as effective as careful scrutiny to understand that this is President Clinton's blueprint for the mother of all bureaucracies. His policy wonks love it, since it could well be the most complex single piece of legislation ever offered in the history of U.S. government.

None of which should be surprising, considering the track record of the principal architect of the President's plan, Ira Magaziner, the mad genius. While an undergraduate at Brown he produced a reform plan for the University that was about the same length as the President's bill. While a consultant to the Governor of Rhode Island he designed an industrial development plan that was only 300 pages shorter. (When the voters in that state discovered that old line party hacks and influence peddlers stood to profit in both power and money, they rejected it out of hand.)

That Mr. Magaziner is a wizard of sorts, few would dispute. He has an undeniable gift for involute mazes containing systems within systems, subsystems within these, and so on, *ad infinitum.* His mindset seems to have been shaped by some of those intricate computer games. Try to follow the money train in the Ernst & Young flow-chart and I think you will agree it is a kind of Dungeons & Dragons approach to health care reform, with layered bureaucracies and fiefdoms. The appalling design almost appears to be an attempt to re-invent one of those old bureaus of the former Soviet Union.

Messrs. Clinton and Magaziner would respond, I am sure, that physicians are only concerned about protecting their incomes and that any objection to the proposed system from our profession is only thinly disguised greed. But they know as well as we do that the power of the purse confers to its holders the power over medical decisions and treatment options.

Mrs. Clinton is an intelligent, persuasive lady but she has protested a few too many times that all her husband seeks for physicians is to free them of economic considerations so that we may practice medicine in a pure, pristine state of total concern only for the patient.

That, in my judgment, is utterly disingenuous. The money flow charted by Ernst & Young will inevitably result, whether intended or not, in multiple levels of bureaucratic control wherein cost will be at constant war with the art and science of our calling. It would be comforting to believe otherwise but we need look no further than the history of Medicare to see some small example of the implicit and explicit dangers to patient care in the burcaucratic nightmare Mr. Magaziner has constructed.

To him, all systems are just systems, amenable to infinite manipulation and reshaping. His talent for intricate design recognizes little difference between systems for industrial development, as in Rhode Island, or in delivery of the most fragile and most precious

service humanity receives.

There *is* a difference, a huge difference, between a system for procurement of military weapons and the procurement of health care. It is Mr. Magaziner's cavalier attitude toward these differences, one shared by Mr. and Mrs. Clinton, that causes such consternation to physicians.

Having said all this, however, I would be remiss in my stewardship to Alabama physicians if I simply dismissed the Clinton bill as totally unworkable and therefore posing no clear and present danger to the finest health care system in the world. While I believe that whatever finally emerges in 1994 will be very different from anything now on the table, I am keenly aware that this is a perilous juncture in the history of our profession.

The Board of Censors and, indeed, all your officers and staff, are similarly persuaded that the best security lies in a rational fear that something similar to this design might ultimately pass Congress. The wisdom of Congress is not a given that we would dare depend on.

Thus, all our discussions over the past year have assumed that the worst might happen. If it does, what damage control measures are feasible? The Board of Censors has addressed this question from many avenues and will continue to do so. We have listened to several experts on managed care and its permutations and have others scheduled.

You will be informed of plans and strategies as they develop. In that process, your Board and Officers are guided by the warning of Thomas Jefferson 205 years ago: ''It is the natural process of things for liberty to yield and government to gain ground.''

To contain and ameliorate that encroachment is our mission.

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The Modern Plague

The physician author of this article requested that his name not be used, for reasons considered good and sufficient by the Editor.

It is the worst of plagues. It knows no season and no boundaries. No mosquito will be identified, no microbe isolated, no vaccine invented to end its reign. It is a pestilence with all the classic trappings of social disruptions, suffering and death — and one terrible, defining difference: we invite it to kill and maim and diminish us. We know how it enters us, and we open the doors to it, lured by the short term pleasure it offers, lulled by the years or decades it incubates before erupting into host-killing maturity.[1]

The plague is substance abuse including alcoholism. Substance abuse plays a major role in one third of all cancer deaths, one half of fatalities from accidents, and one third of AIDS cases. Most murders, rapes, and acts of domestic violence are committed under the influence of drugs and/or alcohol. Research funded by the Robert Wood Foundation marks substance abuse responsible for $240 billion in health and disability costs each year in this country. An Alabama surgeon recently stated, "My biggest income loss is from trauma patients in the emergency room related to alcoholism."

Substance abuse underlies the majority of emergency room admissions in most hospitals. Weekend emergency room admissions in Alabama hospitals are associated with substance abuse, including alcoholism, in greater than 75% of admissions.[2] In the primary care setting, as many as 40% of patients have reported a history of substance abuse.[3] The prevalence of screen positive detection by the department for alcoholism in all new admissions to the adult inpatient service of Johns Hopkins Hospital was 25%.[3] This figure rises in hospitals in urban areas when cigarettes are added to other forms of substance abuse. It is highly likely that Alabama hospitals are experiencing the same plague.

Alabama automobile accident alcohol connected death rates are up more than 36% over the past decade. Nationally, the rate fell 21%. One has to agree with the *Montgomery Advertiser* editorial, July 12, 1993, that "there is nothing abstract about an increase from 263 deaths caused by drunken drivers in 1982 to 359 such deaths in 1991." This deadly record failed to impress the Alabama legislature significantly enough to change the bill changing the legal definition of drunken driving. Clearly, both the legislature and the physicians who develop medical school curriculum need to take a close look at educational efforts in chemical dependency.

A conspiracy of silence complicates the solution to this modern plague. This conspiracy is analogous to the banishment of leprosy patients during the middle ages. A prime example of silence is the minimal curriculum allocated to chemical dependency training in medical school. "Within our secrets lies our disease" is the basis for our failure to resolve issues surrounding substance abuse. Education in the disease concept of addiction makes silence and secrets unnecessary. Brief physician counseling can improve the course of many patients with substance abuse problems.[4] It is most important for physicians to begin to look at their approach toward this disease.

Physicians need to accept that substance abusers have behavior characteristics that sometimes test our highest commitments to our patients. Placing principles before personalities enables the physician to understand behavioral manifestations of the disease. Their unpleasant behavior usually resolves quickly as the offending drug is removed. Denial, minimizing behavior, and blaming others are common defense mechanisms displayed by the substance abusing patient that should be anticipated and recognized by the physician.

As with the patient in the clinical setting, the physician himself may experience denial, minimizing, and intellectualizing behavior towards symptoms in which he is uncomfortable to confront. The physician then becomes a prime object of successful manipulation by the substance abusing patient.

More educational efforts in substance abuse/alcoholism are needed to combat this modern plague. An estimated 28.1% of the U.S. population suffered from a mental or addictive disorder, according to a one year study published in a recent issue of the AMA's *Archives of General Psychiatry*. This implies that many patients presenting in a physician's office may have mental or substance abuse disorders that are not recognized. The modern solution to this aged plague is to put away the archaic attitudes of the past, place the current issues on the table, and encourage educational efforts beginning in medical school and continuing throughout the physician's professional career.

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Appropriate Use of H_2-Receptor Antagonists

*Colin W. Howden, M.D., F.R.C.P., F.A.C.G.**

INTRODUCTION

The four H_2-antagonists currently approved for use in the United States are listed in Table 1. In terms of their pharmacology, all are competitive antagonists of histamine at the H_2-receptor. This receptor is situated on a wide variety of organs and tissues throughout the body but its only proven physiological role is in the stimulation of acid secretion by parietal cells. H_2-antagonists compete with histamine for receptors on the parietal cell. Therefore, the principal pharmacological action of H_2-antagonists is reduction of acid secretion. They are more effective in reducing basal acid secretion during fasting or during sleep than in suppressing daytime, food-stimulated acid secretion.

The Food and Drug Administration (FDA) has granted approval for the use of H_2-antagonists in very specific indications which are listed in Table 2 (from Physicians' Desk Reference, 47th Edition, 1993). The use of H_2-antagonists in duodenal ulcer, benign gastric ulcer and gastroesophageal reflux disease (GERD) will be considered briefly in this article.

On review of Table 2, it will be noted that certain conditions are not listed. In particular, none of the H_2-antagonists is approved for the treatment of patients with bleeding peptic ulcers. This may come as a surprise to many practitioners since these drugs are often administered intravenously to patients admitted to hospital with upper gastrointestinal hemorrhage. However, a recent large randomized controlled trial (RCT) failed to show any significant advantage of high dose intravenous famotidine over placebo in this situation (Walt et al., 1992).

The H_2-antagonists have been extensively investigated in preclinical and clinical studies and in post-marketing surveillance. They are of proven efficacy in those conditions for which they carry an approved indication. In addition, they have an excellent record of safety and tolerability.

Duodenal Ulcer

H_2-antagonists are currently the most widely used drugs in the management of duodenal ulcer. A list of approved dosage schedules is given in Table 3. Note, however, that each can effectively be given as a single dose taken in the late evening or at bedtime in duodenal ulcer. For a detailed discussion of different dosage schedules and associated healing rates, the reader is directed elsewhere (Jones et al., 1987; Feldman & Burton, 1990a, 1990b).

In numerous RCTs, the H_2-antagonists have been shown to be superior to placebo in healing duodenal ulcers and in relieving ulcer symptoms. There are no important differences between existing agents in their performance. Healing rates of around 80% are typical after four weeks of treatment with cumulative healing rates of around 90-95% after eight weeks using the now conventional single evening dosage schedules.

Duodenal ulcer is, of course, a chronic relapsing condition. No treatment, aside from successful eradication of infection with *Helicobacter pylori*, has been shown to significantly alter the natural history of this condition. Therefore, relapse of duodenal ulcer is inevitable in most patients once treatment with an acid-suppressing drug is withdrawn. This has led to the highly successful marketing of these drugs for the continuous maintenance treatment of duodenal ulceration. Each of the four currently available agents is approved by the FDA for this indication (Table 2). For this indication, they are given in half the dose initially used for ulcer healing (viz. cimetidine 400 mg, ranitidine 150 mg, famotidine 20 mg, nizatidine 150 mg), with the dose being taken in the late evening. Using this treatment strategy, cumulative annual relapse rates for duodenal ulcer have been reduced from 70-80% to around 20-30%.

However, at least half of all patients with duodenal ulcer have only one or two relapses per year indicating

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Discover The Elegance Of A Hybrid



At first glance, it's the ***beauty*** of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its ***elegance*** becomes apparent—a gentle blend of softness and strength.

At first glance, it's the ***enhanced performance*** of Vaseretic that catches the eye. But study Vaseretic more closely, and its ***elegance*** becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid ***blending of tolerability and power*** that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

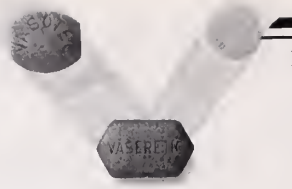
Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality*.



CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General: Enalapril Maleate, Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguna and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy shuuld be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy, Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate: Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide: Teratogenic Effects. Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5. 6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate: Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension ur heart failure with no apparent preexisting renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitur-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions, Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide: When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test (for chromosomal aberrations), or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy, Pregnancy Categories C (first trimester) and D (second and third trimesters): See WARNINGS, *Pregnancy, Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings, Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC, but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest, myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*), pulmonary embolism and infarction, pulmonary edema, rhythm disturbances including atrial tachycardia and bradycardia, atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure; hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported, a causal relationship to enalapril has not been established. *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—*Body as a Whole:* Weakness. *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia. *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia. *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions. *Musculoskeletal:* Muscle spasm. *Nervous System/Psychiatric:* Restlessness. *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS). *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia. *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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Table 1.
Currently available H_2-antagonists

Approved name	*Trade name*	*Manufacturer*
Cimetidine	Tagamet	SmithKline Beecham
Ranitidine	Zantac	Glaxo
Famotidine	Pepcid	Merck
Nizatidine	Axid	Eli Lilly

that not all patients require continuous maintenance treatment. Precise indications for the use of maintenance treatment in duodenal ulcer have been debated in the past (Howden, 1989; Wormsley, 1989). My personal recommendation is not to use maintenance treatment routinely. If using an H_2-antagonist for active duodenal ulcer, I suggest that treatment be given for 6 to 8 weeks and then discontinued. Follow-up office visits will detect symptomatic relapses of duodenal ulcer which can then be managed by a further course of an H_2-antagonist in the full healing dose. Patients who have three or more relapses per year may be considered for maintenance treatment. Increasingly, however, these patients are likely to be treated with drug regimens aimed at eradicating *Helicobacter pylori* infection. This is beyond the scope of this article.

Categories of patients for whom continuous mainte-

Table 2.
Approved uses of H_2-antagonists

Cimetidine:
- —short-term treatment of active duodenal ulcer
- —maintenance therapy for duodenal ulcer at reduced dosage after healing
- —short-term treatment of active benign gastric ulcer
- —erosive gastroesophageal reflux disease
- —prevention of gastrointestinal bleeding in critically ill patients
- —treatment of pathological hypersecretory conditions

Ranitidine:
- —short-term treatment of active duodenal ulcer
- —maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers
- —treatment of pathological hypersecretory conditions
- —short-term treatment of active, benign gastric ulcer
- —treatment of gastroesophageal reflux disease
- —treatment of endoscopically-diagnosed erosive esophagitis

Famotidine:
- —short-term treatment of active duodenal ulcer
- —maintenance therapy for duodenal ulcer patients at reduced dosage after healing of an active ulcer
- —short-term treatment of active benign gastric ulcer
- —short-term treatment of gastroesophageal reflux disease

Nizatidine:
- —treatment of active duodenal ulcer (up to 8 weeks)
- —maintenance therapy of duodenal ulcer after healing of an active duodenal ulcer
- —endoscopically-diagnosed esophagitis (for up to 12 weeks)

(Physicians' Desk Reference, 47th Edition, 1993)

nance treatment has been recommended include the elderly, those with other serious chronic medical conditions, those with a previous history of an ulcer complication and those taking non-steroidal anti-inflammatory drugs (NSAIDs). While such an approach intuitively makes sense, there is little scientific evidence to support it. Instead, I would expect to see increasing emphasis on *Helicobacter pylori* eradication as definitive treatment for these groups of patients in the future. This is likely to be more highly cost-effective than continuous, presumably life-long, maintenance treatment with an H_2-antagonist. However, we must await the results of prospective RCTs examining the efficacy, impact and safety of *Helicobacter pylori* eradication in these specific groups of patients.

(Benign) gastric ulcer

There are important differences between the management of patients with gastric and duodenal ulcer irrespective of the treatment used. All patients with gastric ulceration must have careful upper gastrointestinal endoscopy and collection of biopsies and cytology brushings from around the ulcer crater. This is necessary to exclude underlying gastric carcinoma. In addition, follow-up endoscopic examination of gastric ulcer patients during treatment is mandatory to ensure adequate ulcer healing and to further exclude underlying malignancy. Such measures are unnecessary for the management of patients with duodenal ulcer.

As with duodenal ulcer, the efficacy of the H_2-antagonists in the treatment of benign gastric ulcer has been proven by numerous RCTs and confirmed by formal meta-analysis (Howden and Hunt, 1990). Using an approved dosage schedule of an H_2-antagonist, one would expect healing rates of 80-90% after eight weeks (Howden and Hunt, 1990).

There is a strong association between gastric ulceration and the use of aspirin or NSAIDs. When a patient who is taking a NSAID is found to have a gastric ulcer, it is important to carefully review the indication for the NSAID and to critically evaluate the need for its continuation (Howden and Holt, 1991). Most gastric ulcers in patients on NSAIDs will heal on treatment with an H_2-antagonist even if the NSAID is continued. However, it is important to realize that healing will be more rapid if the NSAID is withdrawn (Lancaster-Smith et al., 1991). It is interesting to note that many patients with such non-inflammatory conditions as osteoarthritis can be satisfactorily managed on acetaminophen and therefore do not require NSAIDs (Bradley et al., 1991).

None of the H_2-antagonists is currently approved for use as maintenance treatment in the long-term management of patients with benign gastric ulcer (Table 2). Patients whose gastric ulcers were related to the use of aspirin or an NSAID appear to have a favorable prognosis without any form of maintenance provided that they are able to stay off these medications (Bank et al. . . .).

GERD

The pathogenesis of GERD is fundamentally different from that of peptic ulceration. GERD is primarily a disorder of esophageal motility, most often characterized by transient, inappropriate relaxations of the lower esophageal sphincter (LES) allowing the reflux of acidic gastric contents into the esophagus. In addition, patients with GERD have impaired esophageal clearance so that refluxed gastric contents remain for longer in the esophagus. Patients with GERD usually have normal levels of gastric acid secretion. However, it is acid and the related peptic activity which is responsible for the symptoms of the condition and for the damage to the esophageal mucosa. Pharmacological suppression of gastric acid secretion has, therefore, been a mainstay of the management of patients with GERD.

In comparison with their clearly beneficial effects in duodenal and gastric ulcer, the H_2-antagonists have been shown to be less effective in GERD (Tytgat and Nio, 1987). Higher doses may be used in patients with GERD (Table 3) and it is usually necessary to give these drugs twice daily or more frequently. This is an important practical point; single evening doses are usually inadequate for managing patients with GERD. H_2-antagonists can be of value in managing patients with milder forms of GERD. However, even here, they are more effective in controlling symptoms than in healing esophagitis. They are rather ineffective for patients with GERD complicated by significant erosive or ulcerative esophagitis.

The main alternative treatment approach in GERD is the use of the proton pump inhibitor omeprazole (''Prilosec,'' Merck). This drug has been shown to be highly efficacious in GERD both for relieving symptoms and for healing the erosive and ulcerative lesions of esophagitis. In an overview of its use (Holt and Howden, 1991), it was shown to be superior to standard doses of either cimetidine or ranitidine which are the H_2-antagonists against which it has been most frequently compared. Unfortunately, there are no published RCTs comparing standard doses of omeprazole with an approved higher dose of an H_2-antagonist in the treatment of GERD.

GERD is a chronic relapsing condition and omepra-

Table 3.
Approved dosage schedules of H_2-antagonists

Drug	*Indication*	*Dosage*
Cimetidine	Treatment of active duodenal ulcer	800 mg q.h.s. 400 mg b.i.d. 300 mg q.i.d.
	Maintenance treatment of duodenal ulcer	400 mg q.h.s.
	Acute treatment of benign gastric ulcer	800 mg q.h.s. 300 mg q.i.d.
	Erosive GERD	800 mg b.i.d. 400 mg q.i.d.
Ranitidine	Treatment of active duodenal ulcer	300 mg q.h.s. 150 mg b.i.d.
	Maintenance treatment of duodenal ulcer	150 mg q.h.s.
	Acute treatment of benign gastric ulcer	150 mg b.i.d.
	GERD	150 mg b.i.d.
	Erosive esophagitis diagnosed endoscopically	150 mg q.i.d.
Famotidine	Treatment of active duodenal ulcer	40 mg q.h.s. 20 mg b.i.d.
	Maintenance treatment of duodenal ulcer	20 mg q.h.s.
	Short-term treatment of active, benign gastric ulcer	40 mg q.h.s.
	GERD	20 mg b.i.d. 40 mg b.i.d.
Nizatidine	Treatment of active duodenal ulcer	300 mg q.h.s. 150 mg b.i.d.
	Maintenance treatment of duodenal ulcer	150 mg q.h.s.
	Esophagitis diagnosed endoscopically	150 mg b.i.d.

zole is not currently approved by the FDA for prolonged or continuous use. Standard treatment course with omeprazole for patients with GERD give 20 mg once daily for 8 weeks. Some practitioners have chosen to treat GERD patients acutely with omeprazole and then to try and maintain healing with continuous use of an H_2-antagonist. However, this practice is not endorsed by the FDA. In addition, it has not been shown to be particularly effective in RCTs. Relapse of esophagitis is common even on standard doses of H_2-antagonists (Lundell, 1990).

SUMMARY

The H_2-antagonists are an established part of the therapeutic armamentarium. They are highly effective in the specific indications for which they have FDA approval. In my opinion, there is no justification for using them in such non-approved indications as non-ulcer dyspepsia or bleeding peptic ulcer. However, it is clear that much of the prescribing of these agents is for such non-approved uses where their efficacy is unproven.

The excellent safety record of the H_2-antagonists is one compelling reason to support their future change of status to "over-the-counter" medications. This has already happened in some other countries.

I would predict that the other major change in the use of these agents which we will see will be a reduction in their use as maintenance treatment for patients with duodenal ulcer. Pending the results of longer-term efficacy and safety studies and the establishment of safe and effective therapeutic regimens, I would expect *Helicobacter pylori* eradication to become the accepted means of treating duodenal ulcer long-term.

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Demand for New Physicians

Merritt, Hawkins and Associates

At a time when the federal government is considering cutbacks in medical residencies,young physicians are being snowed under by job offers, according to a new survey.

The survey of 219 physicians in their final year of residency, conducted by Merritt, Hawkins & Associates, a national physician search firm based in Irving, Texas, indicates that two-thirds of medical residents receive at least 50 job offers during the course of their residencies. Forty-six percent of residents surveyed received 100 or more job offers during their residencies. Residents surveyed complained of receiving six to seven recruitment calls a day, with some recruiters resorting to tricks such as masquerading as relatives in order to speak with them.

''The idea that America has too many doctors is wishful thinking to anyone responsible for recruiting physicians today,'' said James Merritt, president of Merritt, Hawkins & Associates. ''This survey is a further indication that we have too few physicians, not too many.''

Other results of the survey: 69% of residents expect to earn $100,000 or more their first year in professional practice, 53% of residents would prefer a group practice setting, 78% of residents would prefer to practice in communities of 50,000 or more and 84% of residents believe medical practice conditions will either deteriorate or stay the same during the new administration.

Financial Expectations

Residents' financial expectations reflect the reality of physician earnings today, according to Merritt. Sixty-nine percent of residents surveyed expect to earn $100,000 or more in their first year of professional practice. Specialists surveyed expect higher earnings than generalists, with 48% of specialists expecting to earn $150,000 or more their first year of professional practice, compared with only 6% of generalists expecting to make that amount.

Residents also concurred on the form of compensation they would prefer. Ninety-percent of residents surveyed would prefer an income guarantee or salary as a form of compensation in their first professional position. Only 9% would prefer fee for service compensation, and only 1% indicated a preference for a bank loan.

''When it comes to compensation, financial security is the name of the game,'' Merritt stated. ''The days when physicians would take out a bank loan, hang out a shingle and begin practicing are long gone.''

Residents surveyed also were emphatic about their choice of practice settings, with the majority favoring medical groups. Only 14% of residents surveyed indicated a preference for a partnership, 9% expressed a preference for a solo setting and 7% expressed a preference for an HMO.

''The low level of enthusiasm for solo practice is no surprise,'' Merritt stated. ''The business hassles associated with solo practice have turned doctors off for some time. However, the dearth of interest in HMOs is somewhat surprising. Despite the regular hours and steady paychecks HMOs offer, residents appear to be wary of managed medicine.''

They also are leery of rural practice. Only 7% of residents surveyed would prefer to practice in a community of 15,000 or less.

In addition, residents make their practice plans in advance, the survey indicated. Seventy-seven percent of residents surveyed began a serious job search a year or more before completing their residencies.

''Health facilities recruiting residents should note that if they do not contact residents until their third year, they may be too late,'' Merritt said.

Doubts and Affirmations

Recent political changes have left many residents with misgivings about the future of medical practice. Eighty-four percent of residents surveyed indicated that, based on the new presidential administration, the professional climate for physicians would either deteriorate or stay the same. Only 16% of those surveyed felt professional conditions for physicians would improve. Specialists were particularly pessimistic: 69% of specialists surveyed responded that professional conditions would deteriorate in lieu of the new administration.

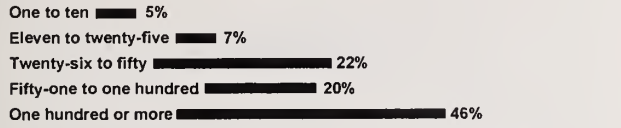
TELEPHONE SURVEY OF 219 FINAL-YEAR MEDICAL RESIDENTS

Conducted January, 1993 through April, 1993

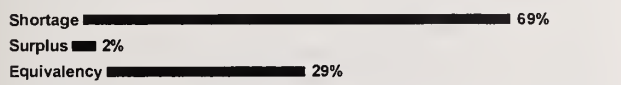
219 Primary Care and Diagnostic/Surgical Respondents

A national sample of final-year medical residents in family practice, internal medicine, pediatrics, obstetrics/gynecology, orthopedics, otolaryngology, cardiology, general surgery, gastroenterology, radiology, anesthesiology, and neurology.

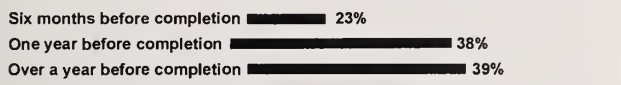
1. **How many practice opportunities have been presented to you, either by telephone, mail or in person, during the course of your residency?**



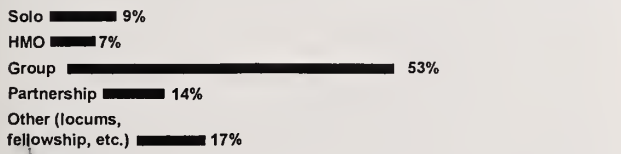
2. **Do you perceive a shortage of physicians in your specialty, a surplus or a supply/demand equivalency?**



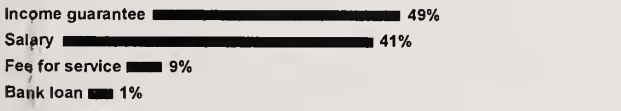
3. **At what point in your training did you begin to seriously examine practice opportunities -- actually obtaining information, arranging interviews, etc.?**



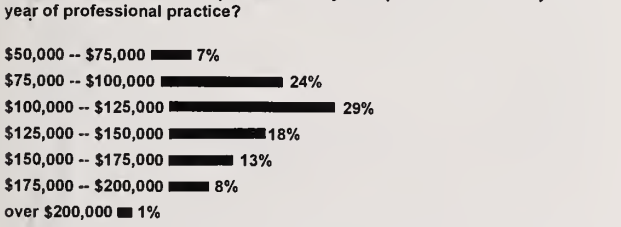
4. **In which of the following settings would you most like to practice?**



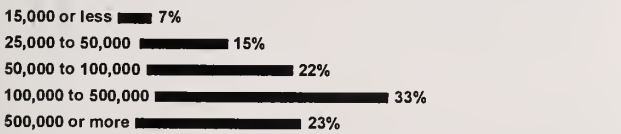
5. **Which of the following types of compensation would you most prefer at the start of your first professional practice?**



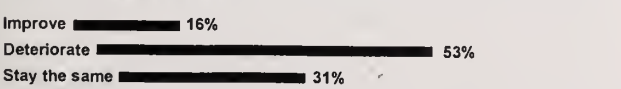
6. **What general level of compensation do you expect to achieve in your first year of professional practice?**



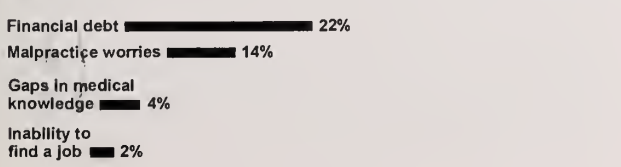
7. **Based on population, in what size community would you most like to practice?**

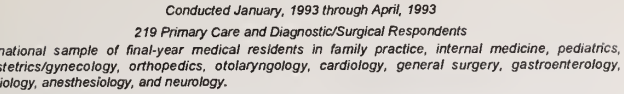


8. **Based on the new presidential administration, do you believe the professional climate for physicians is likely to improve, deteriorate or stay about the same?**



9. **As you consider entering professional practice, what is your primary area of concern?**





10. **If you were to begin your education over again, would you study medicine, or would you choose another field?**

TELEPHONE SURVEY OF MEDICAL RESIDENTS

Conducted January, 1993 through April, 1993

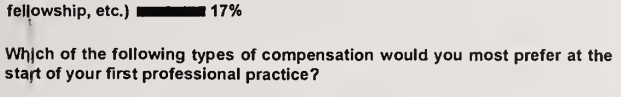
81 Diagnostic/Surgical Respondents

Merritt, Hawkins & Associates' survey of 219 final-year medical residents included surveys of 81 final-year residents in orthopedics, general surgery, otolaryngology, cardiology, gastroenterology, radiology, anesthesiology and neurology. Survey results of diagnostic/surgical respondents are as follows:

1. **How many practice opportunities have been presented to you, either by telephone, mail or in person, during the course of your residency?**

2. **Do you perceive a shortage of physicians in your specialty, a surplus or a supply/demand equivalency?**

3. **At what point in your training did you begin to seriously examine practice opportunities -- actually obtaining information, arranging interviews, etc.?**

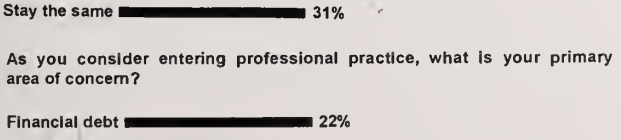


4. **In which of the following settings would you most like to practice?**

5. **Which of the following types of compensation would you most prefer at the start of your first professional practice?**

6. **What general level of compensation do you expect to achieve in your first year of professional practice?**

7. **Based on population, in what size community would you most like to practice?**



8. **Based on the new presidential administration, do you believe the professional climate for physicians is likely to improve, deteriorate or stay about the same?**

81 Diagnostic/Surgical Respondents

Deteriorate 69%
Stay the same 27%

9. As you consider entering professional practice, what is your primary area of concern?

Financial debt 16%
Malpractice worries 15%
Gaps in medical knowledge 1%
Inability to find a job 2%
Doubts about health reform 40%
Doubts about the right medical setting 26%

10. If you were to begin your education over again, would you study medicine, or would you choose another field?

Medicine 81%
Another field 19%

TELEPHONE SURVEY OF MEDICAL RESIDENTS

Conducted January, 1993 through April, 1993

138 Primary Care Respondents

Merritt, Hawkins & Associates' survey of 219 final-year medical residents included surveys of 138 final-year residents in family practice, general internal medicine and pediatrics. Survey results of primary care respondents are as follows:

1. How many practice opportunities have been presented to you, either by telephone, mail or in person, during the course of your residency?

One to ten 3%
Eleven to twenty-five 6%
Twenty-six to fifty 16%
Fifty-one to one hundred 17%
One hundred or more 58%

2. Do you perceive a shortage of physicians in your specialty, a surplus or a supply/demand equivalency?

Shortage 73%
Surplus 1%
Equivalency 26%

3. At what point in your training did you begin to seriously examine practice opportunities -- actually obtaining information, arranging interviews, etc.?

Six months before completion 24%
One year before completion 39%
Over a year before completion 37%

4. In which of the following settings would you most like to practice?

Solo 9%
HMO 8%
Group 51%
Partnership 10%

138 Primary Care Respondents

Other (locums, fellowship, etc.) 22%

5. Which of the following types of compensation would you most prefer at the start of your first professional practice?

Income guarantee 43%
Salary 47%
Fee for service 9%
Bank loan 1%

6. What general level of compensation do you expect to achieve in your first year of professional practice?

$50,000 -- $75,000 11%
$75,000 -- $100,000 38%
$100,000 -- $125,000 38%
$125,000 -- $150,000 7%
$150,000 -- $175,000 4%
$175,000 -- $200,000 2%
over $200,000 0%

7. Based on population, in what size community would you most like to practice?

15,000 or less 9%
25,000 to 50,000 17%
50,000 to 100,000 18%
100,000 to 500,000 31%
500,000 or more 25%

8. Based on the new presidential administration, do you believe the professional climate for physicians is likely to improve, deteriorate or stay about the same?

Improve 24%
Deteriorate 43%
Stay the same 33%

9. As you consider entering professional practice, what is your primary area of concern?

Financial debt 25%
Malpractice worries 14%
Gaps in medical knowledge 5%
Inability to find a job 2%
Doubts about health reform 28%
Doubts about the right medical setting 26%

10. If you were to begin your education over again, would you study medicine, or would you choose another field?

Medicine 88%
Another field 12%

Health reform is the leading area of concern for residents, followed by medical settings, financial debt, malpractice, and doubts about medical knowledge. In a significant departure for most young professionals, only 2% of residents surveyed responded that doubts about their ability to find a job headed their list of concerns.

Despite these reservations, residents affirmed their choice of careers. Eighty-six percent of residents surveyed indicated that they would select medicine as a career if they could begin their education again.

The Search for Security

According to Merritt, the survey underscores the mindset of young physicians today.

"Residents today are coping with a barrage of mixed signals" Merritt said. "On the one hand, they are recruited like star athletes. On the other hand, they feel threatened by government and consumer hostility. Consequently, residents are looking for security, reassurance and a relief from stress. Anyone recruiting residents has to be aware of this delicate frame of mind if they wish to be successful."

Young Physicians Tell Where It Hurts

Final-year medical residents surveyed by Merritt, Hawkins & Associates expressed their opinions on a variety of subjects. Anecdotal remarks were made by physicians...

...On Physician Recruitment:

"Recruiters are everywhere. They call six to seven times a day and seem to have a practice wherever you want to go in the United States." Family physician, Illinois.

"I have received over 1,000 calls from recruiters. Seriously." Family physician, Iowa.

"One recruiter had the gall to call my parents to find out what my plans are when I finish residency." Internal medicine specialist, Maryland.

"I have received two to three mail pieces from recruiters per day since my second year of residency." Family physician, Connecticut.

...On Practice Settings:

"I would like to join a group practice. A decent call schedule is a must because I have to raise a family as well as practice medicine." Family physician, California.

"It used to be possible to go into private practice. Now it's impossible. You can only see a patient for five minutes, and then you have to spend 15 minutes on paperwork." Pediatrician, California.

...On Health Reform:

"I was at the 'Conversations on Health' sessions in Tampa, Florida, which was chaired by Hillary Clinton. They were taking questions from the audience, but they wouldn't take mine because they knew I was a physician. All the government wants to hear is how bad things are from a few hand-picked people." Family physician, Florida.

"If the Clintons were going to reform the legal system, I doubt they would exclude attorneys from the process. How can they reform the system and not include the people who are part of the process?" Obstetrician/gynecologist, Missouri.

...On Medicine as a Career:

"I love medicine. I was a nurse for seven years prior to entering medical school. You have to love medicine to overcome the misperceptions that some people have about it — particularly with the government promoting an adversarial role between physicians and patients. Most people don't understand that doctors

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give up their lives, their youth, everything to become physicians, not to rip people off.'' Family practitioner, Florida.

''The whole medical process is grueling and I feel like I have given up more than it's worth, especially with the changes I believe are coming.'' Obstetrician/gynecologist, Indiana.

''As a doctor, you work for people, not money. If I wanted to make money I would have done something else. I want to be compensated for what I do, but money is not the reason I chose medicine.'' Internal medicine practitioner, Ohio.

Methodology

The survey of 219 final-year medical residents was conducted by Merritt, Hawkins & Associates in order to obtain an indication of the level of demand for the services of physicians about to enter medical practice. The survey also was conducted to obtain information concerning the practice preferences and professional concerns of medical residents.

A national sample of residents was taken from lists generated by a computer data service. Residents from three areas of the country — the West, Midwest and East — were surveyed in approximately equal numbers (about 73 surveys for each region). Residents were called at random. Approximately 2,300 calls were made from January 6, 1993 through April 17, 1993 in order to complete the 219 surveys taken.

Medical specialties selected for the survey were made on Merritt, Hawkins & Associates' perceived level of demand for physician services. The greater the perceived demand for a certain specialty, the greater the number of residents in that specialty surveyed. Primary care physicians comprise the majority of physicians surveyed, because there is a perceived greater demand for their services than for the services of residents in other medical specialties. The survey therefore is of most use as a benchmark or signpost for those recruitment firms, hospitals and medical groups actively recruiting physicians.

Completion of the survey and tabulation of results was supervised by Gerry Weipert, director of research, Merritt, Hawkins & Associates.

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by Howard J. Bennett, MD
Dr. Bennett is the editor of *The Best of Medical Humor: A Collection of Articles, Essays, Poetry & Letters Published in the Medical Literature.* Hanley & Belfus, 1991.

Image Analysis of Retinal Reflexes in the Detection of Ocular Disease States

S. Hutson Hay, M.D.
Richard Bryant
Jack Hughes
Keith Parker

In the past several months, we have been excited by the development and use of a photonic sensor to aid in the analysis of ocular disease states (Figure 1). This sensor combines traditional telescope optics with an electronic sensor known as a Charge Coupled Device (CCD). The CCD is a solid-state, two-dimensional array of very small (0.1375 x 0.016 mm) metal-oxide semiconductors mounted so as to received maximum illumination from a visible light source. In our experiments this light source has been the retinal reflex. The semiconductor chips are known as "pixels" and are arranged in a 192 x 165 checkerboard pattern, making the total CCD only 2.64 square millimeters in size.

The function of a pixel is to convert incident radiation into electrical impulses. This is achieved by a process known as the Photoelectric Effect (the same theory which won Albert Einstein a Nobel Prize in Physics in 1905). The light incident upon the CCD is contained in discrete bundles of energy known as photons. When a given photon impinges upon the metal-oxide of the pixel, it imparts energy to the electrons in the outer surface of the metal. If its energy is sufficient, it will liberate the electrons and create an electric current. The magnitude of the current created will be proportional to the irradiance level of the light and thus digitizes the image so that it may be read by computer electronics. The sensitivity of this device is quite remarkable being equivalent to ASA 20,000 speed film with quantitative accuracy.

The capturing of retinal reflexes is achieved through use of a software package that is compatible with the CCD system. The computer software is utilized on an 80386-based PC with a high resolution super-VGA monitor. The software allows the user to change various operating parameters of the sensor. This includes exposure time which may vary from 10 milliseconds to 5 minutes. The software then captures the image and graphically displays it so that it may be further manipulated by the user. The user is then free to process the image as described later in this paper.

In order to augment the analysis, several software programs were written in our office which provide greater graphical resolution of the image. These programs, written in C, provide a three dimensional surface map of the irradiance level reflected from the retina. Thus for each patient a three-dimensional "fingerprint" of the ocular state of the eye is achieved.

This program is allowing us to build a database to categorize disease by image type, and then be used by computer to perform pattern recognition. Pattern recognition is a new and complicated field in computer science and typically relies upon artificial intelligence techniques to provide accurate analysis of images.

We have reconfigured an instrument first reported in 1985 (1) and are now using photonics and image analysis with this new instrument. These processed images reveal information not seen with the old optical-film presentation. More importantly the computer can quickly take measurements of the image to deter-



Figure 1.—Generated Retinal Reflex Photometer: This instrument easily fits into an examining lane and measures 60 cm long.

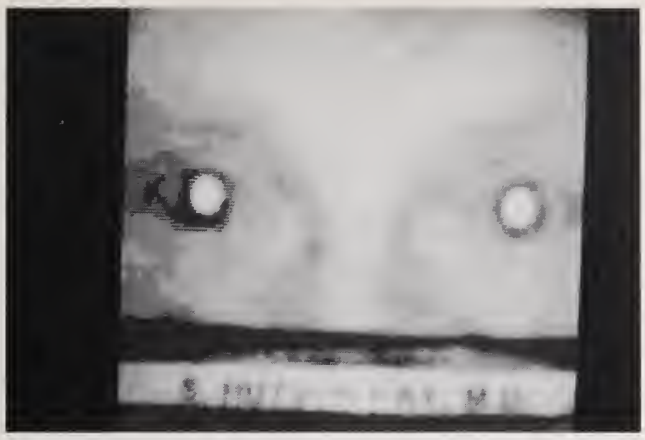


Figure 2.—Normal, 20/20 Eye: A characteristic pattern is found in this condition, and is characterized by a central marking corneal spike with an even and uniform surround of light exiting the pupil. This results in a bull's eye appearance on the two dimensional presentation.

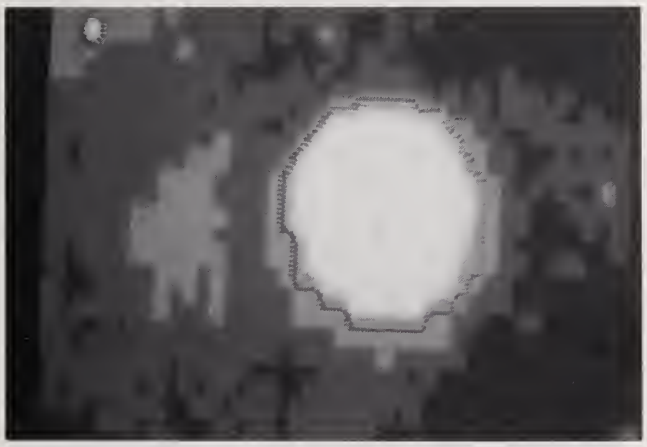


Figure 2a.—Zoom of right eye, two dimensional presentation.



Figure 3.—Normal 20/20 Eye: This topographical presentation demonstrates the intensity of irradiance exiting the pupil on the vertical axis.



Figure 4.—Normal 20/20 Eye: Cross section of the irradiance on the vertical axis.



Figure 5.—Myopic Eye: This pattern is characterized by a bright crescent at the top of the pupil. The degree of myopia seems to be correlated with the size of the crescent.

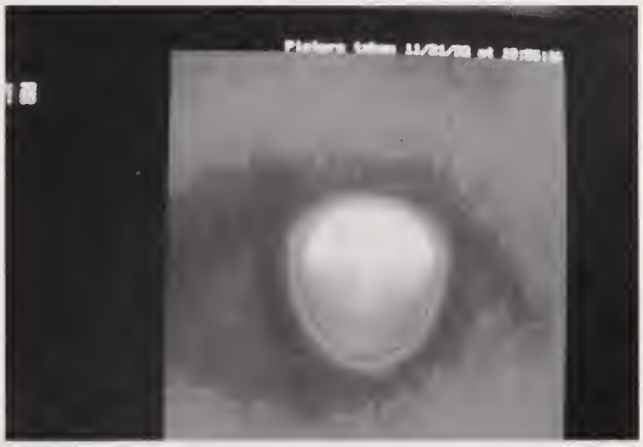


Figure 5a.—Myopic Eye: Zoom of myopic eye demonstrating greater detail.

mine such things as percent of light reflected, rate of change of light from one point to another, irregularity of shape, and light concentration in specific areas of the eye. Additionally this technology allows different images to be "co-added" or subtracted.

We are correlating image patterns that correspond



Figure 6.—Hypermetropic Eye: This characteristic pattern is represented here with the bright crescent at the bottom of the pupil.

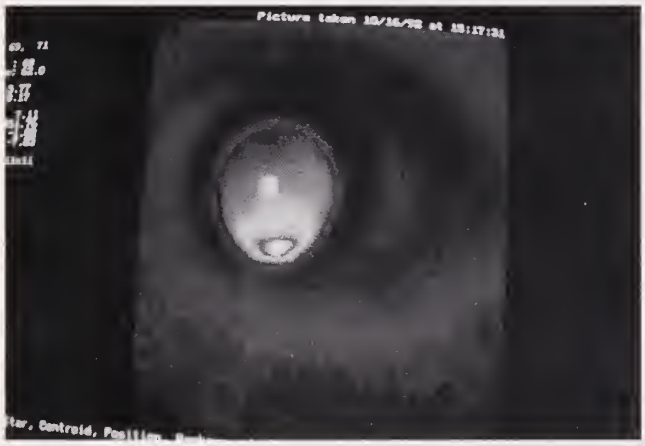


Figure 6a.—Hypermetropic Eye: Zoom of an hypermetropic eye demonstrating detail.

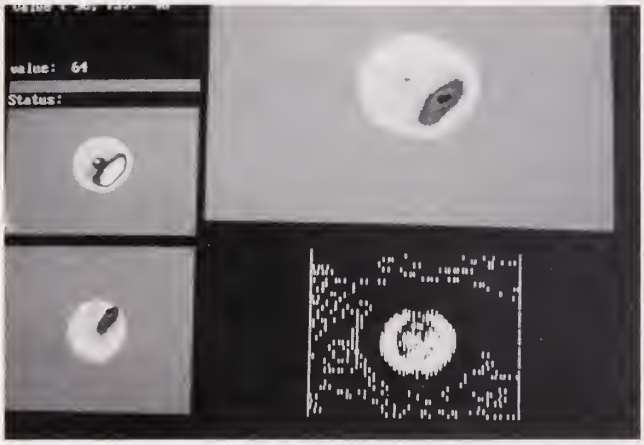


Figure 7.—Oblique Astigmatism: This image is a computer enhancement of a two dimensional image of this condition. It demonstrates an unusual off of vertial reflex.

with known ocular disease states such as refractive errors, amblyopia, retinal detachment and cataract. The normal eye is easily recognized and has a distinctive

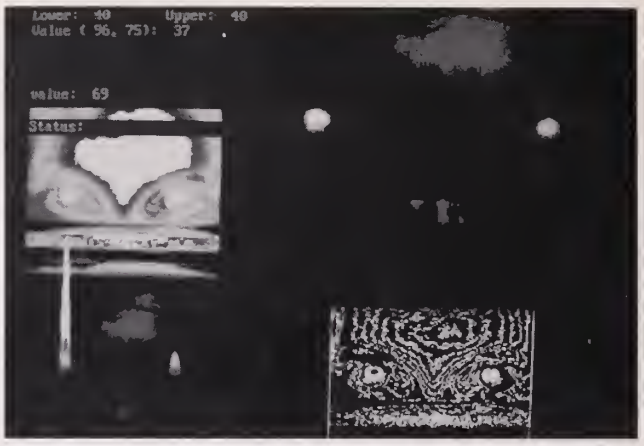


Figure 8.—Anisometropic Amblyopia: This image is a computer enhancement of an image of a person whose eye on the left was normal and who had a great amount of myopia on the right. In this situation the vision from the right eye does not "fit" with the vision in the left eye because it is larger and more out of focus. The brain simply can not integrae these two images and so ignores the one poorer quality and the eye becomes amblyopic. This computer enhancement clearly demonstrates the optical difference between these two eyes. The lower left presentation plots the irradiance of reflected light on the vertical axis. The greater the reflection, the greater the refractive error.



Figure 9.—Homocystinuria with dislocation of lens

pattern with our instrument (Figures 2, 2a, 3, 4). Currently we are attempting to create a program that will allow the computer to recognize these characteristic patterns and distinguish them from abnormal patterns. Abnormal patterns that weem particularly easy to recognize are myopic (Figures 5, 5a), hypermetropia (Figures 6, 6a), oblique astigmatism (Figure 7), anisometropic amblyopia (Figure 8), homocystinuria (Figure 9) and cataract (Figures 10, 11, 11a, 11b, 11c, 11d).

The main determinant in detecting ametropia (refractive errors) is a simple comparison of the position of the spike of light reflected off the cornea and the



Figure 10.—Cataract: The right eye demonstrates the pattern of a cataract characterized by a dark degradation of the retinal reflex.



Figure 11.—Cataract: the degradation from the cataract is more central. Cataracts are in both eyes.



Figure 11a.—Cataract: Zoom of image left eye to demonstrate more detail.

''centeroid'' of light being reflected off the retina. A greater concentration of light being reflected off of the top correlates with nearsightedness; light reflected from bottom of eye correlates with farsightedness. The degree of this shift upward or downward seems to



Figure 11b.—Catatact: This is a computer enhancement of 11a at light level 63. The lower right hand image is a contour study and demonstrates the cataract as a white central crescent.

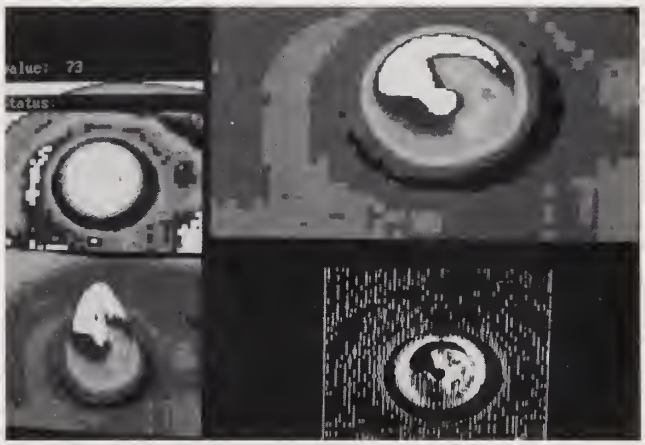


Figure 11c.—Cataract: Image identical to 11b but at light level 73. By comparing the contours of 11b and 11c it is apparent that, at bright light levels, the cataract obstructs more of the pupilary opening.

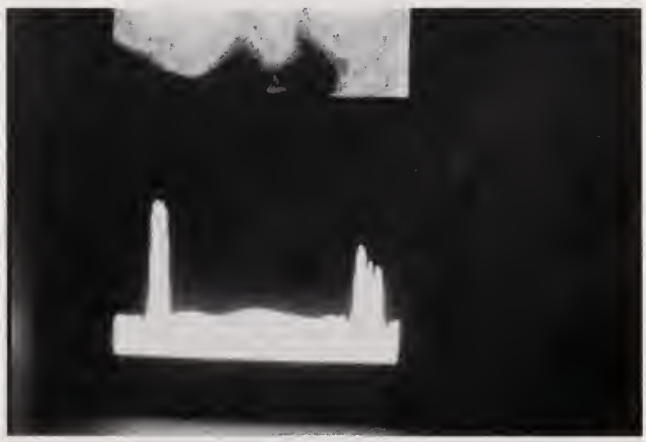


Figure 11d.—Cataract: Cross section of the reflex of a cataract on the patients left side. The sawtooth pattern results from the interference of the cataract as the light attempts to pass through it. Apparently there exist considerable differences in the optical density of a lens with a cataract.

correlate with degree of error. Amblyopia results in a generalized change in light intensity one eye to the other and cataract produces a defect in the retinal reflex. Other patterns are observed such as dual centers. We do not know the meaning of these patterns but continue to look for a correlation with disease states.

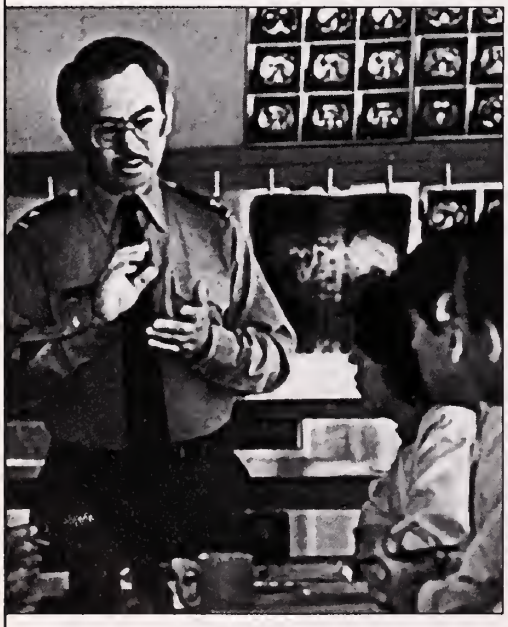
A great advantage of this instrument appears to be its ability to screen in an objective fashion without requiring a response from the patient. This makes it quite suitable in evaluating preverbal children. This instrument also appears to be able to document the existence of and follow the course of cataract development. There appears to be some degree of correlation between the objective finding using this instrument and those light levels that seem to be most difficult to patients with cataract.

The use of electronic imaging with a CCD and image processors may well have implications in any branch of medicine where photography is utilized. We continue to explore its ramifications with our instrument in ophthalmology. Other fields such as radiology might find this real time image processing advantageous.

Reference

1. Hay, S. Hutson, et al., Retinal Reflex Photometry as a Screening Device for Amblyopia and Preamblyopic States in Children, Southern Medical Journal 76:309, 1983.

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The Hemodynamic and Metabolic Influences of L-Name in Endotoxin Sepsis

R.M. Smith, MS, A. Rizzo, MD, E.D. Graves III, MD, J.R. Fletcher, MD, PhD, FACS.
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Introduction: Endotoxin sepsis has been shown to diminish vascular responsiveness to catecholamines in vivo via the nitric oxide pathway. There is some evidence that nitric oxide production is increased in patients and in animals administered *E. Coli* lipopolysaccharide. Nitric oxide synthase inhibitors (NOSI) have been shown to reverse this hyporesponsiveness, causing an increased mean arterial pressure (MAP) and systemic vascular resistance (SVR) in septic animals. However, NOSIs have also been shown to reduce cardiac output and increase metabolic acidosis in the canine endotoxin model. In this study we shown that N^G-nitro-L-arginine methyl ester (L-NAME), a nitric oxide synthase inhibitor, transiently improves MAP and heart rate (HR) which are altered during sepsis without improving tissue perfusion.

Methods: Male Sprague-Dawly rats were anesthetized with halothane and metofane. The jugular vein and carotid artery were cannulated. Control animals (n = 7) received a 1-cc bolus of sterile saline alone. Endotoxin animals (n = 25) received 10mg/kg of endotoxin (lipopolysaccharide W *E. Coli*) at time zero. L-NAME/endotoxin animals received 300μ molar of L-NAME 20 minutes prior to the administration of 10mg/kg endotoxin at time zero. MAP and HR were monitored continuously for four hours. Arterial blood gases and plasma samples for TXB, PGF, and PAF were determined by radioimmunoassay at times (0, 5, 60, 120, and 240 min).

Results: L-NAME caused a significant ($p < .05$) increase in MAP (time 0 (t_0);169 ± 10, t_5;159 ± 13, t_{30};142 ± 8) and a decrease HR (t_0;315 ± 27, t_5; 312 ± 34, t_{30};370 ± 8, t_{60};391 ± 30) in septic animals when compared to control MAP (t_0;124 ± 4, t_5;127 ± 8, t_{30};131 ± 10), HR (t_0;430 ± 66, t_5;454 ± 60, t_{30};441 ± 38, t_{60};456 ± 41) and endotoxin MAP (t_0;133 ± 10, t_5;137 ± 10, t_{30};137 ± 10), HR (t_0;422 ± 38 t_5;420 ± 52, t_{30};439 ± 38, t_{60};447 ± 44) alone. There was also a significant ($p < 0.05$) decrease in bicarbonate levels (HCO_3; 18 ± 2mm/l) and carbon dioxide levels (PCO_2; 24 ± 3 mmhg) when compared to endotoxin (HCO_3; 20 ± 3mm/l, $PCO_2$28 ± 5mmhg) and control (HCO_3; 25 ± 2mm/l, PCO_2;31 ± 4mmhg).

Conclusions: Endotoxin administered to our rat model produces hypotension, tachycardia, and a metabolic acidosis. A single dose of L-NAME appears to transiently reverse the hemodynamic vascular hyporesponsiveness caused by endotoxin sepsis. We concluded that nitric oxide produced during sepsis may be necessary to help maintain adequate tissue perfusion. Blocking nitric oxide synthase improves the vascular hypporesponsiveness as seen with the increase in MAP. This effect appears to be more detrimental in the septic animal because it increases metabolic acidosis

probably because the increase in MAP and SVR decreases cardiac output.

DNA Repair in Insulin-Secreting and in Noninsulin-Secreting Cell Lines from a Rat Insulinoma

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The possible causes, cures and prevention of diabetes are continuously being researched. It has been hypothesized that environmental toxins might be one of the responsible, causative agents of diabetes; a likely mechanism of action for some of these agents is through interaction and damage of DNA. Therefore, the primary interest of this laboratory is to examine how environmental agents, such as the N-nitroso compounds, damage DNA and how this can cause disease. N-nitroso compounds are found in air pollution, cigarette smoke, and various food-products. N-nitroso compounds, such as streptozotocin (STZ), have been found to be diabetogenic and have prompted studies suggesting that some forms of diabetes may result from environmental beta cell toxins. These toxins damage DNA by alkylation and cause base modifications and depurinations. If the damage caused by these compounds was not repaired, improper transcription, translation and replication would occur leading to cell malfunction. DNA repair mechanisms restore original DNA, allowing it to function properly. This project was designed to study the damage and repair to genomic DNA caused by the N-nitroso compound, methylnitrosourea (MNU). One enzyme thought to be partly responsible for the repair of alkylation damage is poly(ADP-ribose) polymerase (PADPRP). In clinical trials, inhibition of PADPRP by nicotinamide and 3-aminobenzamide (3AB), has demonstrated both therapeutic and preventative effects upon diabetes within rodent subjects. These results have led us to examine the role that PADPRP has on DNA repair in beta cells. In order to test this theory, two cell lines, isolated from the same beta cell tumor, were used: the RINr 38, an insulinoma which actively transcribes the insulin gene, and the RINr B2 cell line which does not transcribe this gene. The amount of damage and repair was assessed by a nucleoid assay using neutral sucrose gradients on cells that had been treated with MNU for one hour and then allowed to repair for either 0, 8, or 24 hours. The results showed repair was indeed significantly inhibited in both cell lines after 8 and 24 hours. These findings suggest that PADPRP is an enzyme essential in the mechanism of excision repair in alkylated-damaged DNA.

PCR and Southern Analysis of Normal and Glioma DNA from Human Brain Using Minisatellite Probes

R. Lee Dean, B. Mukerji* and Y.M. Bhatnagar Departments of Structural & Cellular Biology, and *Medicine, University of South Alabama, College of Medicine, Mobile, AL 36688

Of the primary brain tumors, gliomas are possibly among the most common type found in adults. Available data indicate that due to the highly aggressive nature of these tumors and the lack of any effective treatment, the median survival time is rather short (a year or less) following initial diagnosis. Therefore, an increased understanding of the molecular changes in these tumors may lead to improvements in their diagnosis and treatment.

DNA probes recognizing telomeres and minisatellite repeats have been useful in determining polymorphism in the telomeric and subtelomeric regions of human chromosomes, respectively. We have recently shown that the normal brain telomeres may be resolved into two different populations by the use of a pulsed-field gel electrophoresis (PFGE) procedure; and that the glioma DNA preparations may be characterized by varied amounts of the two telomere populations. However, no comparable data is available for the minisatellite repeats. The present investigation was undertaken in order to determine whether genomic rearrangements in gliomas can be detected by the use of repeated DNA probes, [$(GACA)_4$, $(ACTG)_4$, $(CAC)_5$, $(CAG)_5$, and $GTG)_5$].

PCR amplification with primers for the repeated elements failed to reveal any changes in the minisatellite loci present in the glioma DNA. However, the two telomere populations in the brain may be discriminated from each other, in the *EcoRI* digests, by their differential hybridization pattern to probes recognizing (GACA) and (CAC) repeats. The location of one of these repeats, $(CAC)_5$, near the chromosome terminus was suggested by their sensitivity to *Bal31* exonucleolytic activity.

Innervation of the Hypoglossal Nucleus by Neuronal Subgroups in the Rat Parabrachial Complex

K.M. Krist, L.D. Aldes
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During respiration the tongue performs a vital role in maintaining a patient airway. The mechanism controlling this activity is unknown, however, it is likely that respiratory signals affect hypoglossal (nXII) motorneurons which subsequently innervate tongue muscles. Be it that nXII motorneurons are not intrinsically

rhythmic and do not receive any primary afferents, respiratory drive signals to nXII motorneurons must be derived from respiratory centers in the brain stem. The objective of this study was to determine if the parabrachial complex (PBC), a major respiratory center in the pons, projects directly to nXII. Our strategy consisted of conducting retrograde and anterograde axonal transport experiments to determine if any or all of the PBC projects to nXII. The retrograde experiments aimed to label PBC neurons by injecting wheat-germ agglutinin conjugated to horseradish peroxidase (WGA-HRP) into nXII. In the anterograde experiments, injections of WGA-HRP or *Phaseolus vulgaris*-leucoagglutinin (PHA-L) were made to label PBC axonal terminals in nXII. Thirty-six female, Sprague-Dawley rats (175-200 g) were used in this study. Rats were anesthetized with a combination of ketamine hydrochloride (2 mg/kg, IM) and acepromazine maleate (0.05 mg/kg, IM). Animals were secured in a stereotaxic frame and the brain stem was surgically exposed. Glass micropipettes (10 um tip diameter) were backfilled with transportable markers. After placing the micropipette stereotaxically into the brain stem, iontophoretic injections were made by passing positive direct current of 2-6 uA, pulsed at seven (7) second intervals or continuously, for 8-30 minutes. Animals were reanesthetized after 1-8 days and fixed by transcardinal perfusion with aldehydes. Forty-to-fifty um thick sections were cut through the brain stem and reacted enzymatically with tetramethylbenzidine for localization of WGA-HRP or immunocytochemically for PHA-L localization. Mounted onto subbed slides and dehydrated, the tissue was examined in the light microscope for retrogradely labeled neurons in the PBC or for terminal labeling in nXII. The results were as follows: WGA-HRP injections into nXII resulted in retrogradely labeled neurons in one subgroup of the PBC, the Kolliker-Fuse (KF) nucleus. Labeled neurons were distributed bilaterally, but mainly ipsilaterally. WGA-HRP and PHA-L injections into KF displayed terminal labeling in nXII bilaterally, but mainly ipsilaterally. These results establish that the PBC innervates nXII in the rat. Moreover, KF is the only component of the PBC that can affect tongue muscle activity. By demonstrating a direct KF-nXII projection, given the well known involvement of KF in respiratory activities our hypothesis that KF controls the upper airway muscles during respiration.



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Mrs. William Hall
A-MASA, President

Leadership Today

The 1980s were a golden decade for the not-for-profit world. Some 170,000 new organizations were born, employing more than 7 million people and utilizing more than 120 million volunteers.

The fact that more people are volunteering than ever before in U.S. history gives the Medical Alliance and Auxiliaries a golden opportunity to achieve its goals. But to take advantage of the opportunity, you need to respond to today's changing volunteer.

How have volunteers changed? They are more apt to give their time to task- and time-specific work — for example, to two hours a week on a domestic violence hotline, not a three- or five-year commitment. Todays volunteers are also more result oriented — less interested in making and following rules and more interested in hands on projects that help people. And todays volunteers want to know what's in it for them, their spouses, their families, and their neighborhoods?

Leaders of these volunteers need to accommodate to these changes. They need to be flexible, focused, and farsighted.

Mrs. Ruth Johnson, a former AMASA President and American Medical Association Alliance President gave the following speech on Leadership Qualities at the 1993 AMASA Convention. Mrs. Johnson is an outstanding leader and a very gracious lady. We thank her for sharing her views, her guidance, and her experience.

I will begin today by saying that I know you have all read your President's article in the December issue of *Alabama Medicine* on Leadership. She said far more about leadership than I can possibly tell you.

I will list some of the qualities of leadership that I think are important: Here are 5 personality types, perhaps you will recognize yourself by your ruling passion:

1. It could be 'control' — you need to be right;
2. Self esteem — you feel superior;
3. Security — you dread rejection;
4. Attachment — you create drama;
5. Justice — You cherish rage.

Your best qualities are valuable assets — in moderation. But too much of a good thing can be excess baggage, a psychological blind spot that keeps getting in your way. For instance — you are well informed, but can't admit it when you're not. You are as well organized you make everyone else a slave to your schedule. You are marvelously warm and entertaining but you are not happy unless you are the center of attention.

Judith Sills in her best seller 'Excess Baggage' getting out of your own way explains excess baggage — making some mistakes over and over, needing to be right, feeling superior and setting your standards too high that you nor anyone else can meet them. *THIS IS EXCESS BAGGAGE.* Some have never known failure, others learn from their mistakes and keep their dreams alive.

Know your protocol. What is protocol? It is the way we do things. Every good leader knows how to conduct a meeting, how to open the meeting, how to introduce the officers and or guests, how to introduce the speaker.

How to conduct business, how to close the meeting. This is protocol — how to make everyone comfortable.

Do what you can with what you have is good advice. If you are gifted, reach out to the less gifted. If you are praised, praise others. And of all the things you wear, your expression is the most important. If you are anxious it will reflect to your members. If you are unsure they will know it. Have you ever noticed from time to time the ones at the head table often wear expressions that are less than pleasant, bored, stern, 'sour', I have heard it expressed. Lighten up the head table.

Whatever job you are assigned, do it better than anyone else has ever done it, as I recently heard a young football coach say 'when they call your number you had better be ready' and from the oft quoted Mark Twain 'always do it right, this will gratify some and astonish others.' But you will make mistakes for poor judgment is always with us, but don't hesitate to acknowledge that you have made a mistake. Do not be like the M.D. under whom my husband trained at the Mayo Clinic who often told his residents 'Gentlemen, I may not always be right but I am never wrong.'

You have to have enthusiasm, work ethic, motivation and a goal. And once you have honed your skills developed this capacity for leadership here is an essential: willingness to serve, you owe it to the organizations to which you belong, to your community, and to your church. For we must respond to the needs of others. But you need not do as I have done and have your husband say 'so you have to be president of everything?' In looking over my college year books recently and noting the activities I seemed to have entered into I must wonder now 'how did I ever have time to make the grades to graduate when I was young and foolish.' And I have had little failures (they pale into insignificance now) for I have learned not to look back for that is over and cannot be changed. Don't dwell on mistakes, but be aware of where you went wrong and don't do it again and again. As Omar Khayyam in the well known and loved 'Rubaiyat' wrote these wonderful words of advice that have become one of my beacons as I have worn these many roles of leadership 'The moving finger writes; and having writ, Moves on: not all your piety nor wit Shall lure it back to cancel half a line, Nor all your tears wash out a word of it.'' If you can meet triumph and disaster and treat these just the same you can meet all the problems and joys of leadership and remain true to yourself.

Good leaders are not afraid of idealism and are eager to create, to blaze new paths and at the same time bring out the best in others. Change is welcome and leaders are prime movers, learn from the past but let it go. Leaders don't burden themselves with old ideas, prejudices, habits or processes. The inspired leader looks for the opportunity in change and tries to understand it even if some do not like it. There will be criticism but beware of those who tell you things 'for your own good' it won't be and never is, or to those who eagerly offer 'constructive criticism' it never is, really. Taking risks is a vital part of leadership, but do not expect perfection. Eighty percent of success in life is having a positive attitude. Trust yourself and others, remember that one person with a belief is equal to 99 who have only an interest.

Have a sense of humor, it is said that if you take yourself too seriously no one else will. Leaders know that life and business are no joking matter, but they have the ability to keep things in perspective. They are self-accepting and can laugh at themselves. When stress and pressure become a problem, the leader's sense of humor gives everyone a momentary 'emotional vacation' so that the situation can proceed with balance and clear direction.

Commitment is the primary word for leaders. Leaders determine a course, make a plan, then have the self-discipline to follow through in spite of obstacles. Leaders stay in the game long after others give up. Most quit too soon. Remember what a wise person once said 'one who develops ten people is greater than one who does the work of ten' but a word of advice 'do not ask others to do what you may have never done yourself or are not willing to help them do it.'

Developing people to their maximum potential and allowing them to do their job is the greatest source of benefit to any organization. A good leader accepts defeat with good humor and tries again. If you must accept a less than the top job when you think you have earned it, do what you are given with good humor and do it well. This has happened to me too, so carry on and 'don't ever let them see you cry.'

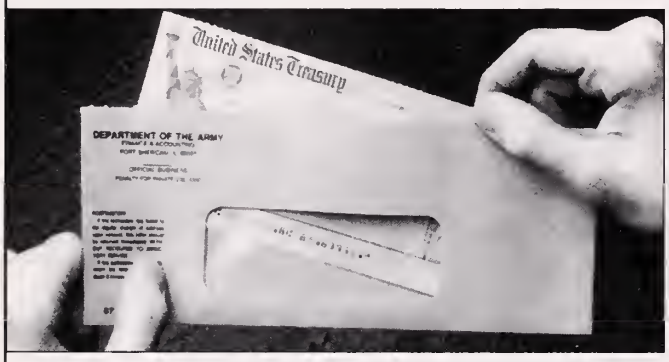
And be sure to make friends along the way — be a friend and help out wherever you can, for you will need friends and *how* you will need them. A French writer is often quoted 'do not walk before me for I may not follow, do not walk behind me for I may not lead — but walk beside me and be my friend!

So accept leadership, give it your very best effort, prepare, prepare, and prepare — GO FOR IT AND YOU WILL BE GLAD YOU DID!

And finally — do not hesitate to ask for advice — for you never know it all — never, and listen to those WHO HAVE WALKED THE WALK FOR THEY CAN TALK THE TALK!

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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin, the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine. Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli,* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General.**)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive. gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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December 1993 Vol. 63, No. 6

Alabama Medicine

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

While congressional leaders say some manner of health care reform will pass, support for Clinton's convoluted proposal has eroded; Americans are increasingly apprehensive of a Washington fix.

Through a Glass, Darkly -- Dr. West, p. 4

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Americans have a love-hate attitude toward the federal government, an ambiguity that was never more evident than in their attitudes on health care reform.

The Federal Dichotomy -- Mr. Conner, p. 2

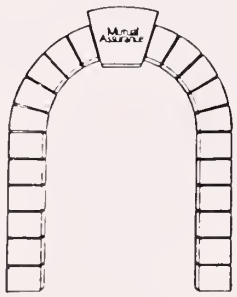
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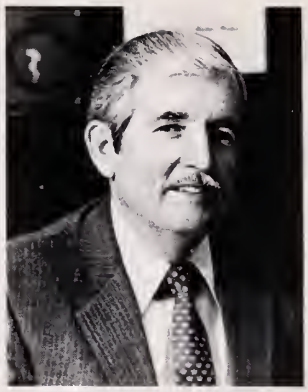
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MAR 17 1994

EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

The Federal Dichotomy

There is a stark ambivalence in the way Americans regard government. They cannot decide whether government is their rich and benevolent uncle, who can be touched for help in times of trouble, or whether that government is the hated enemy at the gates of personal freedom.

Even patriotism is skewed by this dichotomy. Most of us are thrilled by the sight of the flag in a military parade or solemn ceremonies at Arlington. But when that same flag is displayed in the offices of the Internal Revenue Service, say, it stands for oppressive government bureaucracy.

We love our country in the abstract but not always in the particular. Congress, for example, is held in abysmally low esteem by a substantial majority of Americans; so is the federal bureaucracy in all its reaches. For many years many Southerners ranked the U.S. Supreme Court as almost as evil and threatening as the Soviet Union.

We Americans don't think Washington can do anything right but in time of real stress we turn to it anyway. In all the recent national disasters, victims of hurricane, flood and earthquake immediately looked to the federal government for help, but then denounced the inefficiency and inadequacy of the response — too little and too late. Governor Pete Wilson of California, responding to President Clinton's promise that Washington would pick up **some** of the bill for the recent L.A. earthquake, rather testily demanded that Washington should pay the **whole** bill.

When we say, as we are given to saying, that government can't do anything right, we don't mean the Army, the Marines, the Air Force, the FBI, the Bureau of Public Roads, the National Parks, the National Institutes of Health, the Public Health Service and so on. In point of fact most of us, if pinned down, might grudgingly concede that the U.S. government **can** do a few things right. If we are then asked for examples of what the government has made a hash of, a high percentage of us would probably say, well, the U.S. Postal Service is one good example.

Despite the whipping-boy status of the Postal Service, it may well be the cheapest and most efficient on earth. I cuss the postal service too, almost as if it is considered un-American not to. But under threat of grave bodily harm, I might be compelled to admit that I consider the mails a daily miracle.

This ambiguity was present at the creation: the Founding Fathers were torn between their desire for a stable and enduring government and their fear of government power. They wanted the central government to be just strong enough to survive but not too strong. In all the checks and balances they integrated into the system design, distrust of government is abundantly evident. One of the founders went so far as to say that the only legitimate function of Washington should be "to guard the shores and deliver the mail," period.

They wanted it recorded for all time that the U.S. government was a creature of the states and not the other way around. They feared all centralized power; Jefferson even went so far as to distrust cities, believing as he did that civic virtue and the spirit of liberty could exist only in the agrarian heart. God lived in the countryside; the city was the devil's abode. (This belief was at least one element in the South's secession, as it is in Northern California's expressed desire to secede from Southern California, in Staten Island's serious proposal to free itself of Manhattan, and so on.)

A year ago, there was all but universal agreement that the American health care system was in crisis. This was the virtually unchallenged predicate for some

kind of Washington fix. But a year of delay and debate has given second thoughts to both Washington and the nation. The rapid jump from the crisis mindset to the maybe-not demurrer can be directly attributed to the love-hate relationship in which government solutions are viewed by all of us. Americans were attracted at first by the seeming promise of something for nothing, then disenchanted by the slower realization that it might not be free after all and, in any case, could turn into one huge mess. Ira Magaziner's bewilderingly complex, 1,300-page reform bill did nothing to allay those fears.

Cautious members of Congress know from bitter experience that the public is notoriously fickle. Americans may pronounce health care reform a national imperative, then quickly turn against whatever solution finally emerges. In the recent memory of Congress is just such a 180-degree turn — on the Medicare catastrophic amendment, hastily enacted by popular demand then hastily repealed by popular demand.

They also know that the California Governor was being typically American when he said the federal government should pay the whole cost of the earthquake. Even a good Republican sometimes forgets that the federal government is all of us. On the other side, of course, is the widespread public belief that Southern California is an unsustainable development in an uninhabitable desert region that will be forever rocked by Mother Nature's determination to cast out the arrogant intruders, by fire, mudslide, military retrenchment, earthquake and fruit fly.

While most Americans have the greatest sympathy for the victims of the recent disasters, many do not feel they should be billed for the consequences of human folly. And that feeling will inevitably arise in the coming public debates over some form of national health insurance. Why should God-fearing, law-abiding Alabamians be asked to pay for the exorbitantly expensive consequences of rampant teenage pregnancies, drunk driving, ghetto gang wars, homosexual love, and all the direct and indirect health care impacts of the obscene drug culture? And suffer the dilution of their own health care benefits in the process?

This may be the year when millions of Americans will appreciate the wisdom of the ancient proverb: "The mere existence of a problem is no proof of the existence of a solution." Or at least not a solution which entails federal take-over.



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PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

Through a Glass, Darkly

A funny thing happened to President Clinton on the way to his State of the Union speech to Congress in January — the earth shifted under his feet on his centerpiece issue of health care system reform.

The fault lines had been there all along but not pinpointed with any precision: it was known that his long delay in presenting his plan had given voters and legislators alike time to catch their breath and realize that the President was proposing a truly radical, and reckless, transformation of the finest health care system in the world into a design more to the liking of Ira Magaziner, whose heart belongs to the European model.

The sheer bulk of the complex plan was enough to give pause even to those Americans who had been seduced during the '92 campaign by Candidate Clinton's promise to suspend the laws of gravity and economics to provide all citizens with permanent health coverage, either for free or at a price so cheap as to be beyond rational quibble. He would do this principally by squeezing out fraud, waste and abuse, only later finding it necessary to mug senior citizens of some of their Medicare benefits.

It took a while, but the public slowly became disenchanted, not with the **concept** of health care reform, the pollsters tell us, but with President Clinton's version of it. A major factor in the growing disillusionment was the plan for powerful regional health care alliances and an omnipotent national health board. The average working man or woman wants bureaucracy cut back, certainly not increased.

Also, people began wondering how state alliances could effectively handle all that money when state legislators have not been notably successful handling considerably less in their annual budgets.

Rightly or wrongly, Americans may have less trust in locally run bureaucracies than they have in those in Washington. For one thing, the Washington variety never seems to run completely out of operating funds, whereas state programs often do, as evidenced by the almost routine proration of education funds, the frequent shortfalls in Medicaid in virtually every state, empty coffers in public health, and so on. In many of these cases, the public has come to understand, Congress mandates state services but provides no funding.

What would happen, taxpayers began to worry, if an alliance is poorly administered and goes belly-up? This anxiety was adroitly exploited by the commercials of the Health Insurance Association of America. Thus, about the time Mr. Clinton returned from a survey of the L.A. earthquake he was to discover some threatening political plate tectonics right there under the White House. The subterranean forces were vividly described by one national publication (*U.S. News & World Report,* Feb. 7, 1994):

". . . The electorate is gripped by a massive ambivalence complex . . . regarding health care. Citizens feel good about their own doctors but think the system is rotten. They welcome change, but nothing too dicey or disruptive. If anything, this divided opinion is growing as the public focuses on the details of the health care debate.

"The euphoria is over . . . and as people think they might actually get a new plan, it elevates the contradic-

tions. The main source of weird mixed signals flowing into Washington is the public's love-hate relationship with government . . . There is an enormous suspicion of government . . . but people understand it is the only institution out there with the power to make fundamental changes. . . .

''At the same time, the public believes Washington is full of pushy, inept scoundrels. Only 1 in 4 Americans is willing to pay higher taxes to upgrade the health system, and 4 out of 5 believe any new revenue will be squandered. . . .''

These are certainly mixed signals from the electorate but Congress is tuned-in nevertheless. One of the power brokers in the House, Henry Waxman of California, said: ''There isn't a majority in the House for **anything** at the moment.''

And yet the opinion in Washington is overwhelming that some kind of health care reform will be enacted this year. Against the background of all these conflicting public attitudes, it is difficult to guess how that will be achieved. When you consider that some 700 health care lobbies effectively cancel each other out, it is unclear how Congress could find common ground on anything at all.

It would be dangerous to assume that this early impasse is good news for physicians, implying that nothing will happen. Some very thoughtful people in both parties, as well as in the leadership of our own profession, warn that this would be the worst possible scenario: this may well be a one-time opportunity that, if muffed, may not recur for a generation.

There is much to be said for this view. Yet, an even more calamitous result would be a jerry-built hodgepodge designed to be all things to all points of view. That is a fair definition of chaos, I believe. In any case, the American Medical Association was well advised by its House of Delegates in December to assume a less forward position and to prepare the profession's bulwarks for whatever wild charges may eventuate this year.

In the crazy climate prevailing in Washington, the classic military dictum may have been reversed: the best offense is a good defense, for the time being at least. There will be ample time as the year progresses for a realistic counter-offensive. The complexity of the issue at this juncture is matched only by its fluidity. But only an Ira Magaziner believes, if only he does, that the most vital fraction of the U.S. economy can be demolished and then redesigned in a few hundred hours of brainstorming by even the brightest policy wonks.

From the very outset a year ago, when Mrs. Clinton assembled her secret task force on health care reform, it was evident that this Adminsitration had far too much blind faith in textbook theoreticians to the exclusion of those with practical, hands-on experience and expertise — namely the AMA.

At a recent teleconference, Democratic Congressman Jim Cooper of Tennessee, principal author of a rival reform proposal he calls ''Clinton Lite,'' was asked to explain this attitude. His response would have done credit to the late Will Rogers:

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OUT

*By Robert Lokey, M.D.**

They all ask the same questions.

"Are you enjoying your retirement?"

"What're you doing with yourself — fishing?"

"Are you playing a lotta golf?"

"Do you miss it?"

You get the drift. There are few interesting variations on these general themes. It wouldn't be so bad, if I thought the questions were sincere and honest explorations of *my* specific time-endeavors under the opportunities of freedom from practicing medicine. I don't think that.

Instead, taking into account the sort of automatic utterance the tone of these enquiries have, the almost vapid, no-eye-contact countenance of the usual inquirer, I have come to believe the questions mask some deep-seated concern on the part of the questioner beyond superficial interest or curiosity.

Let's assume this premise is correct. What could this be?

If the inquiring conversant means, by use of the word "retirement," the commonly accepted ideas — which include withdrawal from occupation or business, or withdrawing into seclusion or privacy. . . in any case, withdrawing *from* something — then I can imagine the question(s) is a probe to learn a little more about an area of concern, an unchartered domain that *may* lie ahead for the asking person that, somehow, suggests a possibility for vulnerability.

This will not be surprising to most readers — even if it has not been consciously focused on before. Physicians, for example, are broadly gregarious and rarely pursue their careers in isolation — even the most esoteric laboratory branches require *some* assistants. The idea of voluntarily moving away from a pursuit one has been committed to for many years, that provides utilization of one's time, mental abilities and ego-fulfillment [to say nothing of economic security] can and does, I suppose, alarm some physicians. And there is *pleasure,* of course, for most in successfully carrying out the functions being a physician equips us to do. Why would anyone abandon such a hard won and satisfactorily occupied place?

Well, lately, circumstances called "hassle factors" have been offered as bona fide reasons to *consider* retiring; the hostile milieu of malpractice accusation has been around long enough now to warrant inclusion as a "tradition" of medicine and there has always been the reality that there comes a time to *all* in the profession when the burst of new information, the development of refined technical advances, along with decreasing stamina, concentration and productivity conspire to convince the individual physician the time has come.

Clearly, the accidents of life — illness, altered family circumstance, the interposing of other callings. . . to name a few — are well recognized events that take the practicing physician out of the arena but we speak, here, specifically to the decision to voluntarily stop doing medicine.

For most working physicians [and I include here practitioners, teachers and researchers] *medicine* has been a consuming component of existence, since entry into medical school. Most complex disciplines entail this, whether *law, architecture, engineering, journalism* or *art* (and countless others), but the particular feature of medicine — at least for those who practice — is the obligation to be available. The significant word in this statement is "obligation." To be sure all the other activities listed above carry the same responsibility, but there are built in respites. Teaching assignments rotate, there are scheduled gaps. . . many of the others are so cognitive they can be done in isolation and at one's desired pace. To be good at medicine means to be *at* it, responsible to demand and conscientious as to outcome. Leisure time is at a premium.

The gradual development, beginning in the 1950s, of partnered then grouped practice of doctors was, in large measure, to off-set this absence of leisure time. . . as leisure, increasingly, became a major component of the American way of life. Rotation-of-call is a pattern of medical practice that has come about within our life time. It is, today, one of the two essential features determining success in recruiting new physicians; the other, of course, is the level of income to be anticipated.

6 Timothy Trace, Anniston, AL 36201.

*(205) 237-8226. [Dr. Lokey, retired from general internal medicine, is a freelance writer — Ed]

Recreational skills and hobbies — such as golf, fishing, tennis, water-sports and skiing; woodcrafting, gardening, automobile mechanics to name but a few — fill the hours of leisure for many people, while others turn to more sedentary pursuits like genealogy, painting or sculpting. The concern seems to hover just beneath the conscious level of most: Is this enough to satisfy me, when I am *completely* at leisure?

Which brings us back around to the meanings of words and the realities of conditions. *leisure* cannot mean, in the context of retirement, "absence from work or duties" because almost every retiree one talks with comments on how *busy* they are. From my own personal experience I can testify to the accuracy of the comment. But this busy-ness hinges on the basic nature of the individual and perhaps *here* is where some unconscious concern over "how it is" motivates the questions listed at the beginning.

There are folk — many of them physicians — whose search of self have settled them comfortably into the position that *who* they are and *what* they do are the same. For them, *being* is being _____ [*doctor, lawyer, merchant, chief,* etc.]. Clearly, in this situation *retirement* could be devastating and should probably be avoided.

On the other hand, those of us who say of themselves "I am so-and-so and I do such-and-such," will find, in a life of many blessings, retirement to be the ultimate one. Freedom from obligatory action provides the possibility for one to pursue pathways to completeness. . . to a rounding out, finally, of just *who* one really is. Whether by reading and contemplation in solitude, or by reaching out to others in a different way, or by defining self by previously unexpressed skills, whatever the chosen path — pursued with the vigor available — leads toward an enhanced awareness of self.

Notice is taken, I'm sure, of the avoidance of mention of *money.* This has been purposeful because the luxuriousness of the state of retirement was not the content of these thoughts. Needless to say, the accommodation to the use of resources, just as to one's time, is required; the trappings necessary for the individual must, of course, be the determination of that individual.

So — when the next person you meet says to you "Are you enjoying your retirement," realize the deep content of the innocent-sounding question and reassure them with a knowing glance and a firm *"YES."*

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100 Consecutive Headaches

*Mary Margaret Northem, RT**
*Thomas A. Gibson, M.D., FACR**
*Harrell E. Cox, M.D.**

100 consecutive cases of CT headscans performed for the primary diagnosis of headache, were analyzed. In our institution headache is by far the most common clinical diagnosis given when head CT is ordered. We wanted to evaluate the composition of this group as well as the frequency of demonstration of intracranial pathology.

MATERIALS AND METHODS: Our department uses worksheets to assist the radiologist in the evaluation of CT scans. The technologist performing the scan records a history on the worksheet and discusses it with the radiologist prior to the study to determine the type of examination to be performed. If necessary, the radiologist interviews the patient. In choosing cases for this study, we looked at worksheets on consecutive head CT scans with the diagnosis of headaches. Cases with positive neurologic findings or sudden onset of headache with change in sensorium were excluded. 100 cases in which the sole or primary diagnosis was headache were selected. These are consecutive cases except for vagaries in the selection process by which cases that appear to have more complicated histories were excluded. The examination performed in all of these cases consisted of 1 cm thick contiguous slices obtained from the skull base to the vertex in the axial plane. The studies were performed using either a GE 8800 or Sytec 6000 CT scanner. Data was analyzed relative to age, sex, race, pathology and ordering physician.

RESULTS: There were 68 females and 32 males. The female/male ratio is 2.125 to 1. There was one black (female). The black population in the drawing area of this institution is estimated to be in the range of 10 to 15 percent. Ages range from 9 to 86. There were 6 positive examinations as follows:

3 Paranasal sinus disease
2 Neoplasms
1 Intracerebral hemorrhage

18 physicians ordered these examinations:

3 ordered from 10 to 15 head CT's
4 ordered from 5 to 9 head CT's
11 ordered from 1 to 4 head CT's

DISCUSSION: If one eliminates as pathology the three cases of sinus disease, the incident of positive head CTs with the primary symptom of headache is 3 percent. Sensitivity and specificity are so low that they are not worth calculating. It is interesting that women have more than twice as many headaches requiring CT examination as do men and that this is an unusual indication for head CT in blacks. The lesions demonstrated followed the pattern of sex distribution (two female/one male).

HISTORICAL NOTE: Twenty-five years ago, a similar study was done in this institution regarding routine x-ray examination of the skull. About 15 years ago, a similar examination was performed looking at radioisotope brain scans. The incidence of positive findings was less than five percent in each of these retrospective reviews. It again appears that, "the more things change the more they remain the same." It may be that only the price increases.

Presented at the Meeting of the
Jackson County Medical Society
December 9, 1993

*Jackson County Hospital
Scottsboro, Alabama 35768

Mercedes Medicine

Ralph B. Pfeiffer, M.D.

Medical care for the Medicare patient is reaching the point at which we can no longer pay for all that we can provide. Over 30 million Americans are of Medicare age, more than the entire population of Canada. Surgical procedures and medical therapy that was once considered ill-advised and questionable in elderly patients is now commonplace and successful.

During my residency training, it was unusual to perform an elective procedure on a Medicare patient unless it was life or limb-threatening. Today, the only criteria utilized in deciding on medical or surgical therapy for these patients is their ability to survive it.

The exponential increase in the cost of medical care for those patients compels us to look for fiscal answers. Rationing of this health care resource would seem to be immoral. However, unless reasonable restraints are placed on our health care dollar, *severe rationing will occur* because the entire system will collapse under the burden of economics.

We as clinicians *prioritize* our care and treatment of all patients, but particularly the Medicare age group. We unconsciously factor in age, multiple medical and surgical problems, as well as short and long-term prognoses, in deciding on therapy as well as intensity of care.

For these reasons, the following Prioritization of Care Index or POCI is proposed:

1. The POCI number will be determined as follows: POCI = Age − DRG Code #'s added together, divided by chronological age:

$$\text{POCI} = \frac{\text{Age} - (\text{DRG\#1} + \text{DRG \#2} + \text{DRG 3, etc.})}{\text{Age}}$$

2. Each DRG-code will be assigned a numerical value developed by a committee of health experts, both physicians and non-physicians. This number will be from 1 to 100 and be based on the complication, prognosis, etc of each DRG. For example, coronary artery disease (64713) might be assigned 24.

3. All medical and surgical treatment currently has a CPT-code number. Each CPT-code number would be assigned to a *level* of *intensity* of *care*, or LOIC. For instance coronary artery bypass surgery, would be assigned #0.70%. This would mean that a patient would have to have a 0.70% or greater POCI number for Medicare to *pay* for coronary artery bypass surgery. Patients whose POCI is from .0 to .25 might receive only expectant care (i.e., pain management, IV fluids, oxygen, home health care, hospice care, etc.). Others would fall in between these two extremes.

The POCI would be calculated on the day of admission and updated every day so that this index could go up or down depending on the progress or deterioration of the patient's course during hospitalization. As an example:

$$\text{POCI} = 80\ (\text{Age}) - \frac{(15 + 12 + 6) = .007 \text{ or } 70\%}{80\ (\text{Age})}$$

This patient would qualify for all medical and surgical care that has been assigned a 70% number or *less*. If this patient subsequently develops acute renal failure (DRG of 40) while in the hospital, his POCI# would then be reduced to 9%.

Although at the outset this appears to be health care rationing, we make these same decisions on patients every day. One only has to walk through any intensive care unit in the United States to comprehend and understand that the vast amount of health care dollar is being spent on patients who are at the end of their lives. If there was an infinite amount of financial resource to provide for health care for not only the elderly but for all patients, this entire proposal would not be necessary. However, the economic facts are going to dictate otherwise; and it would be better for physicians to take an active, participatory role in this process rather than having some public health professor from Harvard dictate those guidelines.

The Chronically Ill Patient in the Managed Care Milieu

Jacques R. Caldwell, M.D., Editor of Florida Medicine

The chronically ill configure a vast montage of individuals expressing a medley of ailments such as arthritis, mental illness, posttraumatic disability, congenital deformities, hereditary disease, diabetes or AIDS. The group's dimensions are huge; nearly 34 million people have a disabling illness and 40% are less than 65 years of age. Their medical care requirements are substantial. On average, they consume two to three times more health-care resources than age-matched individuals without chronic disease.

The medical needs of many chronically disabled are well met by society. The tort system or workers' compensation covers those injured by automobiles, other accidents or industrial trauma. Medicaid provides for 40% of the AIDS population and Medicare for the elderly. However, there remains a stiflingly large group of silently neglected humans who have been excluded from access to the medical care system by nature of their underlying disease. Traditional indemnity insurance often excludes them because of a high service utilization profile, or denies coverage or charges usurious premiums three to 10 times higher than for the remainder of the population.

Chronically ill people have not been well served by HMOs and other forms of managed care in the past.[1] Unless their plight is recognized by lawmakers their needs will be lost in the catacombs of the new medical bureaucracy the managed competition health care model promises.

Several reasons explain why managed care is iniquitous to the chronically ill.

First, most schemes depend upon gatekeeper systems to control utilization. Since the gatekeeper's reimbursement is tethered to utilization control, there is a disincentive to provide patients with disabling diseases with the extensive resources their conditions warrant. Examinations of the HMO industry confirm that the gatekeeper system neglects the chronically sick.[1,2]

Second, managed care usually positions the primary care physician as a barricade to the specialist. Data show that these physicians frequently overlook the diagnosis of many chronic conditions. Also, screening for early diagnosis is inadequate in the HMO setting. Thus, appropriate referral to a specialist commonly never occurs. Furthermore, primary care physicians, as a group, treat such conditions inadequately.[1-3]

The ineptness of the primary care system to satisfy the needs of patients with chronic illness should not be surprising. These conditions are difficult to manage. If they were easy to treat they most likely would not result in long-term disability. Conditions such as Parkinson's disease, rheumatoid or other forms of arthritis, or depression require constant monitoring of and meddling into the pharmacologic regimens bestowed on any individual patient. Polypharmaceutical cocktails frequently must be employed and knowledge of rehabilitative measures and equipment is mandatory. Attention to collating and altering the myriad, tiny details of the workplace, home situation, the patient's physical activities and emotional status are imperative to maintaining patient independence and productivity in both the social and economic sense. One might more successfully challenge the North Atlantic in a dinghy during wintertime than to expect any physician to master the complex management strategies for all these debilitating conditions. They usually require specialist care—a reality anathema to the managed care concept.

The third practice that makes managed care collide with the needs of chronically ill patients is that the HMO industry has traditionally discouraged their enrollment because of the large costs associated with attending to their medical problems. Recent state legislation as well as the Americans with Disabilities Act have outlawed much of this discrimination so the industry now typically makes transparent gestures to permit their enrollment but subtly encourages disenrollment by neglecting their needs.[4]

How will the chronically ill be served and protected

in a managed competition environment in which cost, not care, and global budgets propel the system?

The initial step is to educate the policymakers responsible for drafting the regulations governing the managed competition process. The chronically ill have unique needs that have to be recognized, addressed, and met. The overriding theme that should guide care is maintaining the patient's independence within society which implies focusing on outpatient rather than inpatient care. It requires recruitment of family members for help and, at times, case managers to address the workplace and home suitability for patient participation. Recognition and adaptation to the principle that chronic disease usually requires life-long, not episodic, care must be incorporated into their management process.

Certain elements should be included within the structure of the entities providing medical care to the chronically ill. Capitation should be excluded because neglect and denial of services are encouraged by such systems. Since knowledgeable, trained and experienced specialists provide more efficient and certainly more competent care to these patients, the system must facilitate, rather than impede, access to specialist care. The same chronic disease will demonstrate idiosyncratic behavior unique to each patient. Appropriate management requires follow-up by the same skilled physician who can recognize the changing nuances in the expressions of a given patient's illness and alter therapy accordingly. Nothing is so devastating to the successful outcome of a patient with a disabling medical condition than lack of continuity of expert care. The style of care must be legato rather than staccato.

The financing mechanism of the new health-care paradigm has to recognize the needs of the chronically ill. Unless premiums are based on community rating, in which the costs are estimated by models that account for care of everyone in a geographical locale, rather than experience ratings, these patients will be battered by practices that discourage their participation in any health plan and leave them disenchanted and medically disenfranchised.

Perhaps Accountable Health Partnerships (AHPs) or HMOs dedicated to the treatment of patients with chronic illness will have to be established. Lessons from the Medicare experiment with Social Health Maintenance Organizations[5] that specialized in the treatment of the disabled elderly may provide useful guidance as to their limitations and successes. The financial design of any specialized plan will have to differ from that of the typical AHP since the cost of monitoring the chronically ill is so much greater than for the general population.

The managed competition model promotes measurement of outcomes of disease to assure and compare quality of care. Measurement of the evolution of chronic illness usually requires years, if not decades, of observation so outcome quantitation will be difficult. Research instruments that focus on quality of life, rather than disease progress, can be adapted as reasonable surrogates for estimating the quality of chronic disease management.

Discussing the needs of the chronically ill has not been prominent in the current debates about reordering our health-care system. In many instances they have been excluded from the current medical care universe. They and their families have been forced to scramble about the social services maze to obtain rudimentary help. These patients are not part of the sociopathic sediment of society. They are fine, but unfortunate, individuals whose special needs deserve incorporation into the future health-care delivery processes.

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Why the Pencil Will Survive

Henry Petroski in The New Republic

The announcement by the Educational Testing Service this week that it plans to replace pencil and paper with computers on its standardized tests prompts a question. Is this:

(a) an end to No. 2 pencils in the exam room?
(b) an end to No. 2 pencils?
(c) an end to all pencils?
(d) none of the above?

The answer—despite the doom and gloom front-page stories in *The New York Times* and *The Washington Post*—is *(d)*. After all, this is not the first time that the sturdy, low-tech pencil has been threatened. Technological advances and materials shortages have written its obituary many times before. And each time, the plucky implement, seemingly on the verge of extinction, left for dead, has bounced back to life.

The modern pencil dates from the middle of the sixteenth century, when a new mineral that made a dark but removable mark was discovered in England's Lake District. The new mineral was called black lead, because it made a blacker line than metallic lead, which had been among the most common means of making a mark on paper without the mess and bother of ink and quill. Black lead also had military applications, especially in casting cannon balls, and so the English mine from which it came was closely guarded and its output regulated. This made the smallest sliver of black lead very costly. Thus the lead, as it had come to be called, was encased in wood not only to keep the fingers clean, but to protect the pricey substance from breaking. The assemblage of lead and wood was called a pencil, after the fine brush known as a *penicillum* that dated back to Roman times.

With the growth of chemical knowledge, pencil lead was found in 1779 to be a form of carbon. It was then given the name graphite, after the Greek word meaning "to write." (The substance that was found so effective in rubbing out pencil marks was called rubber.) When at war with the English in the late eighteenth century, the French could not get pure graphite, and so an engineer named Nicolas-Jacques Conté was assigned the task of coming up with a way of making good pencils out of poor graphite. He found that if he recombined refined graphite with a clay binder, and if he baked the mixture into a ceramic, he could make pencils as good as the renowned English ones. He found, further, that by altering the proportions of graphite and clay, he could make pencils that made lighter and darker marks. Conté used the numbers one, two, etc., to designate different degrees of hardness in his pencils.

Although Henry David Thoreau did not need to take any standardized test to enter college, pencils were instrumental in paying his way through Harvard. Thoreau's father, John, was an early American pencil-maker, and when Henry David could not keep a teaching job after his graduation in 1837, he worked at the family business, seeking ways to improve the product. He developed the French process to such a degree that by the mid-1840s Thoreau pencils were the best made in America, and Ralph Waldo Emerson bragged that they were made right in Concord. Soon, however, the expanding German pencil firms flooded the American market with their less expensive products, and the Thoreaus were driven out of the pencil business.

By the middle of the nineteenth century, the English source of graphite had been exhausted. At about the same time an equally rich and pure source had been discovered in Asia, and the German firm A.W. Faber gained exclusive rights to it. Soon, Siberian graphite became the world standard for pencils, and other manufacturers began to color their pencils yellow and give them names like Mongol and Mikado to suggest that they too originated in Asia. This influence remains today, with about three out of every four pencils finished in yellow.

From the beginning of pencil-making, the quality of the wood has been as important as that of the graphite, and red cedar from the southeastern United States was long the wood of choice. By the early twentieth cen-

HENRY PETROSKI, professor of civil engineering at Duke University, is author of *The Pencil* (Knopf).

tury, however, supplies of red cedar became so scarce that pencil-makers bought old barns and fence posts to stay in business. In time, incense cedar from the western United States was found to be a substitute wood, and that is what is most likely to be in a good No. 2 today. Of late, there has been some concern that jelutong, a tropical rain forest tree, is being used increasingly for less expensive pencils. To counter concerns that pencils are wasteful of resources, one company came out with the American EcoWriter pencil, which uses recycled cardboard and newspaper fiber. Perhaps it will be more readily accepted than the plastic variety of some years ago.

The humble wood-case pencil has survived the exhaustion of its earliest and best sources of graphite and red cedar; it has survived the introduction of the mechanical pencil, the fountain pen, the ball-point; it has survived the development of the typewriter and the personal computer (which killed the typewriter); and it will survive the recasting of standardized tests into a new cyber-tech format. There are some things, simply, that technology cannot improve on. Compared to the handy, durable, effective pencil, the mouse is, well, a mouse.



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As I see it. . .

Paul A. Ebert, M.D., FACS
Director, American College of Surgeons
In the ACS Bulletin

From all indications, it appears that the changes that are likely to occur under any emerging health care reform plan will result in the downscaling of the health care system in this country. In fact, downsizing seems to be occurring even now with independent actions that are being taken by payors, state governments, and individual health care facilities.

Throughout our professional lifetime, most of us have been taught and have learned — probably unintentionally — how to "upsize" the health care system in order to provide the most complete and advanced care for all of our patients. It seems clear that whatever the recommended changes for this country's system may be, our ability to provide unlimited medical care to every patient is not going to continue, and that fact is likely to contribute to the downsizing of our medical care system.

Hospital occupancy continues to decrease, and it appears very likely that hospitals will continue to be subjected to greater pressure to remain financially solvent. In most of the "reformed" health care delivery systems that are being proposed under managed competition — whether HMO, PPO, or industry-directed insurance programs — it appears that fewer physicians will be needed to care for a larger number of patients. At the same time, with the severe restrictions being imposed on funding, it is likely that less care will be provided. Only with time will we actually be able to determine whether the care that is provided is actually less expensive. In any event, the total amount of care, as well as the amount of money spent, is likely to decrease. Obviously, all of these factors will tend to reduce the size of our medical care system.

It is doubtful that downscaling will occur rapidly, but it is very likely that each alteration or modification in our current system will result in some additional reduction in the size of the overall program. One of the biggest problems we have as a profession is the fact that we have never taken an aggressive role in either upsizing or downsizing the system. We have been taught, and we have believed, that each patient deserves the best possible and most effective treatment, and that no one should have to be seriously concerned about the cost of the treatment. It is true that many cost/benefit analyses and cost-effectiveness programs have been attempted, but few of them have had a significant impact unless a payor — or even a state government, for that matter — has seriously looked at the numbers and decided just how much the particular entity could afford to pay for treatment.

One of the most frustrating aspects of being faced with a period of downscaling is that even with the knowledge that it is likely to occur, it is difficult to make recommendations as to how surgeons can prepare for such changes. As always, the answers to such questions undoubtedly vary from one individual surgeon to another, depending upon the size and location of his or her practice, the type of specialty, and so on. Obviously, some surgeons will be affected very little, but others — such as surgeons who provide unusual or very advanced technologic services — may experience a greater impact.

Professional organizations such as the College will continue to evaluate and emphasize the value of the services that are provided by surgeons, and we will do our best to be certain that whatever type of medical care administrative system develops, it will be realistically planned and will include the possibility of providing the best possible service for the patient at the most acceptable cost.

Still, from all indications and discussions to date, we should begin to accept the fact that our medical system will not be as large five years from now as it is today. As I see it, painful as planning for downsizing may be, surgeons, other physicians, clinics, hospitals, and all other participants in our system had best prepare themselves to adapt to the changes that are anticipated. If they can do that, they may very well be less seriously affected.

As a profession, we often have the problem of not wishing to initiate change until it is thrust upon us. Although I am certain that many surgeons do not believe that significant change is likely to occur, I believe that a little preparation and planning at this time might prove to be of tremendous importance if the modifications that are expected to be imposed on our health care delivery system, do, in fact, materialize.

A Tarnished Image

W. Ray Jouett, M.D.
Chairman, Arkansas State Medical Board
in The Journal of the Arkansas Medical Society

[EDITOR'S NOTE: On Friday, March 26, 1993, Dr. Jouett concluded his year as President of the Neurological Society of America by giving the following speech.]

One year ago, Dr. Russell Travis brought to you some disturbing problems concerning reimbursement and legislation at the national level. I do not plan to follow with information such as was outlined at the last Presidential address and would doubt that very little has happened over the past year but, rest assured, a year from now that will not be the case.

I would like for you to think with me for a short period of time, today, concerning the image of the physician, freely admitting that it is badly tarnished, and try to present some thoughts as to the reason the medical profession has the image that it carries today.

The physician in this country, from the early 1900s to at least 1960, was looked upon with great respect, and to a large degree, the physician was thought of as a scholar. He was a confidante and was relied upon as a trusted friend. Unfortunately, that relationship is not maintained today, and I dare say that we are not going to see that type of physician and patient camaraderie in the near future.

Not long ago a poll was conducted by the AMA, which stated that 68% of the people felt that physicians were not really concerned about them. Sixty percent felt the physician's main interest was making money, and some 27% felt the physician's fees were reasonable. Hopefully, it will be worth our time to look briefly at some historical facts, and look at some information that we know from our association with other physicians, look at the education process of the past and the present for the physician, and see if there is anything in that information that could help us understand what has happened with our relationship in the public.

At the turn of the century, there was a large number of medical schools and a sizable proliferation of physicians across this country. There were little, if any, standards that the medical schools followed. There was no accreditation that was of significance. Many physicians, at the turn of the century, "read medicine" with another physician and, after a period of time, he/she was granted a license for the practice of medicine.

Dr. Abraham Flexner was commissioned to make a study of medicine in this country, specifically the medical schools and their curriculum. That report was published in 1910, and from it came a standardization for the educating of the physician. That report has held and been used for approximately 50 years. At the turn of the century, there were 160 medical schools operating in the United States and the quality of the schools had much to be desired.

Following the Flexner report, there was an elevation of the standards of medical education that led to the demise of many of the substandard institutions and was responsible for slowing the pace for the development of new schools. By 1960, the number of medical schools accredited in the United States by the Liaison Committee of Medical Education (LCME) stood at 86. There was a concern in 1960 that we did not have enough medical schools, we were not graduating enough physicians and, because of that stimulus, 40 more medical schools were developed by 1980. Since 1980, there has been one additional school, which brings the number now to 126.

The 126 institutions that now exist probably have little resemblance to the schools that we were organized and reassessed after 1910. As we approach the end of the 20th century, we are all concerned about the plight of medicine, and the question to be asked is are we producing physicians that will perform well in the 21st century.

Prior to World War II, there were fewer medical schools and their concern at that time was to produce physicians. The medical schools were not involved in biomedical and behavioral research, which has been responsible for developing large, complex research institutions and, as a by product, they seem to also produce physicians. Following the development of World War II, there was a rush to develop more physicians. Many people were accepted into medicine who entered the field to avoid military service and also to obtain tuition from the federal government. The pace proba-

bly never slowed following World War II and, perhaps, an indictment could be made in that regard.

In addition to the development of research institutions, there came a demand for health insurance. In the 1960s, everyone seemed to be interested in mobilizing for a great capacity for training health professionals. In 1965, Medicare came upon the scene, and medicine has not been the same since.

I am not a medical educator but have been interested and concerned for some time with what I see as totally foreign to me in regard to the training I received in medical school. I have not yet been convinced that the present method is that superior. Dr. Abraham Flexner, in his exhaustive report for reforms in 1910, outlined medical education that remained well ensconced into at least 1960. Many of you remember well the types of curriculum of which you were exposed.

Flexner's recommendation consisted of the first two years of solid grounding in the biomedical science of anatomy, biochemistry, physiology and microbiology, which was followed by clinically relevant transition courses such as pharmacology, pathology and with some introduction into clinical medicine. The third and the fourth years were exposure to clinical medicine. To some degree, this recommendation by Flexner is still followed, but students are now, at the end of the first year, selecting electives, making decisions on the specialty of medicine of which they will become involved, and so tailoring their remaining time to offer all of the help necessary for that particular specialty. It seems illogical and ludicrous that a student with one year of matriculation would be able to make decisions concerning what he/she is planning to do the remainder of their life in medicine. Also disturbing, if you tailor your training, obviously a lot of other basic opportunities are going to be lost in the well-rounded development of the student of medicine.

One would get the impression that many of the medical students are looking at a highly paid specialty as opposed to being exposed to medicine and then make the decision, which should not come until following the year of internship. Internships have been discouraged, however, some schools are beginning again to utilize the internship as a part of the postgraduate training.

The Council on Graduate Medical Education feels the ideal number of generalists from the medical schools should be at least 50% and would strive for 70%. However, only approximately 30% become family practitioners or primary care physicians. Again, a point to consider is the high paying specialties and the need for someone to fill a slot in a training program, which has not led to good screening of people that are placed in residency training of the different specialities. It would seem with the proliferation of physicians that a better selection of students should occur over the next several years.

There are 1300 hospitals in this country involved in medical education but approximately three-fourths of all of the medical students train in 388 hospitals. In 1992, nearly 16,000 were expected to matriculate at United States medical schools and also, that same year, 15,365 students were graduated, which was somewhat lower than the 16,343 that graduated in the peak year of 1984. The 1992 graduating class is still about double the size of its class in 1960, and continues to increase in the ratio of physician to population. The consequence of this great number has produced a lot of debate. Certainly we can gauge the physician supply, but we cannot gauge the demand for physician services.

Some point to the development that could readily absorb an increasing supply of physicians, such as the aging of the physician population, the emergence of new disease, such as acquired immune deficiency syndrome, the need to staff preventive and health promotion initiatives and change the social policy that extends access to medical care to those currently under served. Some argue that this would lower the cost of medical care. We are all aware that the increased amount of physicians has not lessened the health care costs.

The cost of medical education is not cheap, and medical schools, we're told as a matter of principle, try to take the most worthy candidates for admission regardless of their ability to pay. The cost of attending medical school rose significantly in the late 1970s, probably to some degree because of inflation that was present at that point. The increase in tuition and fees has continued through the 1980s and into the 1990s and, in the last five years, those increases have kept pace with inflation. The median annual tuition at a private medical school is about $19,000 a year and, at a public or state medical schools, it's $6,600 a year and for nonresidents it's $15,000.

Because of the increasing cost, there has been a growing need for scholarship funds and low interest subsidized loans. Loans constituted the major part of $826 million in student financial assistance in 1990 and 1991. More than half of this amount was from the Federal Stafford loans, which is subsidized by the federal government. The interest on these loans is also subsidized while the student is in training or in an eligible deferment program. Another loan of significance is the Health Education Assistant Loan, known as HEAL, with 16% of the loans coming from this

agency. The interest accrues to the borrower as a result of this commitment, and, upon graduation or at the completion of his training, the student has a formidable debt. We return, again, to the medical student who has graduated with outstanding loans, and they are looking for the high yield and high priced specialties. I'm not sure that loaning students this amount of money so that they are encumbered at the time of graduation should be the way to proceed. The public is also aware of the abuse of these loans because we notice publicly of people who are sued by different agencies, refusing to pay back the debt and pay the interest.

It is not my intention to indict the academic institutions nor define people who staff those institutions, nor is it my intention to indict the American Medical Association because they have not done all of the necessary things to brighten the image of medicine. This is a multi-faceted problem that has to be evaluated at many levels.

There are problems with medical training, but there are also problems with the pre-medical training in that many people are denied access to medical education because of their background and training, who would make excellent, caring and compassionate physicians. The MCAT is developed to test the students primarily on scientific memory, and that hardly seems the appropriate way to judge an individual who is applying for medical school when that should be only a small part of his pre-medical educational background. It would seem more logical to omit much of the scientific background material that the pre-medical student has to digest and become more concerned with developing a background in the humanities and the classics, which would bring back to us some of the earlier standing of the physicians who were looked upon as men of learning.

We need to devote the pre-medical part of this education process to educating, not preparing, a robot technician that can recite pages of scientific information. The foundation of the student in the humanities has all but disappeared because this student must compete in the scientific field with his peers at the MCAT level. This was pointed out so vividly in the eloquent address by Jost Michelsen in his Presidential address in 1988.

Having made a bland indictment toward medical education, there are some things that should be inculcated in the medical curriculum: (1) There is a real need in the medical curriculum for lectures, seminars and some inducement to the student to understand his role in the community. The public looks upon the physician as someone who takes but is reluctant to give back to the community, other than what he considers to be his time in the practice of medicine. (2) There needs to be a place in the pre-medical education that deals with basic economics. The physician is looked upon as the poorest businessman in America, and the reason being that he has had no background in economics. (3) There needs to be courses or seminars on the development of relationships with those that are ill, aside from the treatment of disease. The student is exposed to fine, excellent professors who are skilled in their particular field, but many of the mundane activities, such as speaking to the families of the sick are, at times, done by residents and interns. Medical students need to learn how to communicate with families of people that are ill. Physicians that are caring for a patient need to personally speak with the family when there has been a death or there has been a worsening of the patient's condition. Medical students need to learn how to tell a father with six children that his wife has just died or how to tell a father and mother that their six month old child has died. Sending the chaplain to tell them is not the way to deal with the problem. (4) There needs to be classes on substance abuse at probably all levels of the medical curriculum. This is a problem that no one cares to deal with, but it is a recognized fact that 15% of all physicians will, at some point, become incapacitated because of substance abuse. This is an awful waste for anyone, but especially for a physician who has devoted years of study and has years of productivity ahead of him.

It is a realization that medical education cannot foresee all of the problems that need to be addressed and does not have the time to address these problems in the development of the physician. There has to be some help also, on a peer level, and it should be the responsibility of the peers to help the young physician and not be concerned about this physician because of competition. There is a resistance on the part of the established physician to welcome new physicians into the community and discuss with him fees and to help him become involved in the community. This is a responsibility that we bear and, perhaps might be helpful in preventing the obnoxious advertising that goes on even in the daily news, on TV and in periodicals.

State Boards

There is a perception on the part of the American people that there is a "doctor conspiracy" to protect the incompetent physician and this would also include the protection of the physician that is a drug abuser. We see this at many levels, but I think one of the places where we see much of the criticism arising is at the level of the state Medical Boards, which are charged with protecting the citizens against incompe-

tent physicians. Many feel that the state Boards do not do an adequate policing of the physicians they license.

There are certainly plenty of well publicized failures on the part of the present state Boards. In fact, barely one half of one percent of physicians have ever faced any type of state sanction within recent years. The Physician's Data Bank that was opened last year is now being challenged by the public to be made open to anyone that wishes to review it. The patient has also become increasingly interested in doctor watching and, it is my perception, that doctor watching is going to become as popular as watching members of Congress. We all are seeing the results of the public's displeasure with politicians. We will not escape.

The PRO was to be the great watch dog and the public envisioned this, likewise, as being an agency to identify substandard physicians. The public feels that this has failed and, certainly, we know that it has failed because it actually was not set up to deal with substandard physicians but was attuned to trying to detect fraud on the part of the physician and to trying to save money. As you know, it was not successful at either. Because of the fact that the PRO was not cost effective, it is being discontinued and a new force of action is being started by the federal government.

Physician discipline is the end result of the various state medical boards. The boards grant license. They are also empowered to place those licenses on probation and to suspend and revoke those licenses. There are many problems that encumber state boards in handling these problems. If the state boards do not become more active and more aggressive in addressing the complaints of the public, we will see a federal licensing board, which is already in the thinking stage. The state medical boards, at the present time, may not be doing an adequate job but, I can assure you, if the responsibility for licensing and disciplining of physicians is taken over by the federal government, such as presently is being proposed, the public at large as well as the physicians have not seen problems such as this will bring.

There are more and more complaints coming to medical boards each year, and most of these come from consumers. The main complaint that comes to the State Medical Board in Arkansas revolves around the impaired physician, the incompetent physician and the abusive physician. The number that has been given in the past is approximately 1% to 2% of physicians who fall within the classification of the incompetent or the drug abusing physician. This would indicate that we have some 6,000 to 12,000 physicians nationwide that fall within this category. The number is larger.

The impaired physician is much easier to determine than the substandard physician. They stand out among their colleagues much greater. Their families frequently will report them and patients are becoming extremely observant in regard to what may be an impaired physician.

The state medical boards are not alone in their failure to police physicians. Hospital boards of directors and hospital boards are a bit uneasy about sharing any sort of information with the state medical boards. It's amazing to see the way some hospital boards function. They're queasy and reluctant to report an incompetent or impaired physician, knowing that his license may be restricted in some manner. They seek to work out some type of agreement with the physician and usually end up asking him to get some continuing medical education. They work at any method to get the physician off of their staff as opposed to any type of disciplinary action. I read recently where one hospital staff paid off a doctor's mortgage just to get him to resign from the staff.

Some boards have the philosophy that discipline is the way of dealing with the physician. Other boards are more lenient and feel that rehabilitation is the method of handling the problem, and others feel that there is a fine line that can be drawn by utilizing both methods. I'm of the opinion that it is possible to become too involved in the rehabilitative process and overlook the significant and severe problems.

A physician forfeits his right to continue to practice medicine when he abuses the system with alcohol and other forms of drugs and refuses to keep himself competent with continuing medical education. If physicians are not properly disciplined, this will continue to bring criticism. Most boards are more interested in protecting the physician than they are protecting the public. In defense, to some degree, of the state medical boards, many states have laws that hinder and shackle the board in its effort to take action against a physician because of the long litigation process.

State medical boards can only do their duty if complaints are made, if incompetent physicians are recognized and if impaired physicians are brought to the attention of the board. Certainly, the physician's peers are frequently aware of the problem before they surface at other levels and we, as physicians, have long been reluctant to take a stand against a physician that we know is impaired or who, in some manner, is incompetent, just as we have been reluctant to testify against a physician that we well knew had maimed a patient because of his incompetence. This is a criticism that the public has leveled at us and it is due and just.

We, of the medical profession today, are living in the greatest technological age for the practice of medicine that has even been known. As a result of this

technology, we have lost the compassionate, humanistic attitude that physicians of 50 years ago exhibited. As technology improved, we began to lose the skill of applying the art of medicine. We don't seem to have the time to sit and speak with patients. We've forgotten to spend time discussing with the family their concerns and fears.

The materialistic side of the physician is so evident in that we must amass things and we must amass them rapidly so that we enjoy them. The public is well aware that the physician has to belong to the best country club. It is absolutely necessary that he live in the largest home in the city, that he drive the finest automobile. The materialistic attitude of the physician who desires to take less responsibility has helped with that tarnished image. We seem to measure success on the one that survives with the most toys.

Medicine is much like civilization. It's a tough plant and it has roots that extend all over the world. Some of those roots are more developed than others and, from time to time, things come up and strike the tendrils of this plant and they die, but the plant, itself, is not going to die. Medicine is going to change, and it's going to change in the next century as much as it changed in the past century. The opportunities for medicine are beyond description. One of the disturbing things about what may happen in the next century is that we'll have a physician tied to a computer, and he will do computerized medicine and instruct a technician to do the part that he should be doing. That may be what the American people want, but that's not the perception that I have. The American people still want a trusting, capable, kind and compassionate physician.

I have touched upon a few problems that have changed our image in the eyes of the patients and the public over the past few years, and some of the things I perceive may have been responsible for this decline in esteem. The litany of charges that could be added is long, but it is not too late to change and change we must.

When practitioners of medicine come to the realization that medicine is the servant and not the master, then will we return to our rightful place of medicine being a noble profession.

Don't Throw Out the Caring With the Nostalgia

Howard J. Wetstone, M.D. President
Connecticut State Medical Society
in Connecticut Medicine

I opened an office for the practice of internal medicine on Farmington Avenue in Hartford in July 1955. At that time, one doctor in one office was the predominant way to practice. All the seniors (including the rare medical specialists) would sign out to the younger physicians who sometimes covered each other. As a rule we worked seven days a week taking off one afternoon.

My fees were $6.00 for an office visit and $8.00 for a house call (deplored by my seniors who charged 50 cents and $1.00 respectively, when they started out). Sitting up all night in the ER with a patient in pulmonary edema and arrhythmia taking an ECG and subsequent rhythm strips myself (there were no monitors and the intern went to bed at midnight) was worth $25.00. The second day in the hospital brought $10.00 to $15.00 and subsequent visits were $5.00 each. Taking an ECG at home brought $10.00. (Always at 2:00 AM on a winter night, nearly always on the third floor.)

Patients were responsible for their own bills. They and I knew that our relationship included understanding how they would pay for their care. If they couldn't pay they might bring garden produce, freshly baked bread, or, perhaps, do odd jobs around my house, or we might just forget the balance. Once in a while I would receive a request from an indemnity insurance company to fill out a form so that my patient would be reimbursed for what he owed me. Included was a $3 check from the carrier for my trouble.

Those who couldn't afford private care were seen in clinics and on the ward services of teaching hospitals. Their attendings were a mix of the best and brightest of the practicing community and those of us beginners lucky enough to be appointed to the services of our distinguished teachers. Three months a year on the wards of a large general hospital, another three months reading cardiograms at a now defunct municipal hospital, and caring for acute poliomyelitis patients in an isolation unit gave one a great sense of satisfaction in directly helping those who needed help.

Today, some 38 years later, office overhead has more than doubled as a percentage of gross income (from less than 25% to 55% for primary care physicians), primarily due to the complexities of the reimbursement system. Almost all patients are covered by some private health benefit plan or Medicare or Medicaid. The sense of satisfaction in helping people is still there but the relationships with payors are strained. When the payor was the patient we could look each other in the eye and come to an understanding about the treatment plan and how to pay for it or not pay for it as the case might be.

That special relationship between us has changed as the third party has insinuated itself between the first and second party in an often intensive, sometimes adversial, and always impersonal way.

Let us hope that the changes coming in Connecticut and the nation as regards the reimbursement system permit patients to feel empowered as they once were. The same hope applies for their physicians. After all, the interpersonal relationship between our patients and ourselves play a significant role in shaping their treatment response.

Yes, we want all Americans to have access to health care. Yes, anyone who works should have health insurance as most others who work do. In fact, those on welfare or Medicare are also covered. Yes, some degree of ascertainment of outcome is in the best interests of physician and patient alike. Yes, we will cooperate with the officials of our state as they determine what health care reform measures are to be put in place in Connecticut.

Having said that, is it not also reasonable to take steps to preserve the special private relationship between patient and physician? Cannot oversight of the process by government or private third party be in a spirit of cooperation, nonadversial, designed to help

the patients and give them a sense of security about the financing of their care? Can't the third party get out from between the patient and the physician in the private interactions of the treatment process?

In our nostalgia for the past we must not overlook the new concepts of accessibility of care, the expensive advances of high technology, the need for health care reform, and the proper role of the third party payor. But we should still try to preserve some of what was good about the interaction of a responsible patient and a responsible caring physician. It worked in the mid '50s, why not now?

For Whom the Bell Tolls

Arthur L. Eberly, Jr., M.D.
Florida Medical Association President
in Florida Medicine

Does it toll for just physicians, or does it toll for patients also? Or does it indeed toll for the entire medical care complex as we know it today?

If your perspective is the same as mine, you are more concerned over what you didn't hear [from President Clinton] than what you did hear. I heard precious little about tort reform and the cost problems associated with malpractice litigation. I heard precious little about financing mechanisms, other than some ethereal reference to "savings." I heard nothing about single payor systems as a state option, although this is clearly an option according to numerous documents "leaked" prior to the President's address.

I can't help but wonder how the government can save as much as $91 billion on Medicare, presumably by simplifying forms, eliminating fraud and abuse, and increasing managed care, while adding the cost of prescription drugs and long-term care, likely to be astronomical. In addition to these cost multipliers, we know there will be a steady increase in the number of Medicare recipients. I, though Voo Doo Economics was limited to an earlier administration, would certainly agree that large savings can be realized in the care of those under age 65. The development of a single claim form, insurance reforms, including community rating, portability, and large group purchasing power, should help lower insurance premiums. Clearly 100% participation of all segments of the population will also help lower premiums to an acceptable level.

The determining factor in the success or failure of the President's plan may be the degree of participation by small employers and how many large employers opt to self-insure. Success may also depend on the amount of taxes generated by sin taxes and other taxes which may be deemed necessary to assure success.

You may recall that the President also mentioned the responsibility of citizens to smoke less or not at all, drink less or not at all, engage in safe sex or not at all, and drive safely, including motorcycles and recreational vehicles as well as cars. I hope that these lifestyle changes are not counted on for any significant degree of saving. Having said all this, I think we can truly applaud the President's six principles: security, simplicity, savings, choice, quality, and responsibility.

Finally, I suggest a simple maneuver to lower the percent of GNP for health care by 25–30%. This is really a simple procedure and one that others have reported before us. I would suggest that we begin including in our health-care GNP the same items as most other countries around the world. This would eliminate our reporting long-term care, considered a social problem in most other countries, and over-the-counter (OTC) items. OTC items attributed to the healthcare GNP include toothpaste, feminine hygiene products, vitamins, cough syrup, veterinary products, and others, which may amount to as much as 20–25% of the health-care GNP.

Eliminating these two items would certainly lower the percentage of GNP for healthcare in the United States to less than 10% and probably closer to 8.5–9%.

The coming weeks and months will certainly bring change, and we must endeavor to enable that change while preserving the basic tenet of American Medicine: freedom of choice for patients and physicians alike. If we accomplish this, we may well not care for whom the bell tolls.

Fat and Fraud to Finance Reform?

Frank Clark
Executive Vice President,
Los Angeles County Medical Association

Come on now, you're kidding, Mr. President!?

You plan to pay for your health reform package by cutting out waste, both administrative and systemic; stopping fraud; and installing insurance premium caps and global budgets? (I forgot the cigarette sin tax.)

Said another way, you're planning to have a relatively rich benefit package, add 37 million uninsured Americans, offer long-term care and prescription drugs for seniors, subsidize small business, provide insurance for early retirees — and pay for this with a cigarette tax; elimination of waste, fraud, and abuse in the present health system; and further deep cuts in Medicare and Medi-Cal?

"That much fat and fraud in the system there ain't!"

You and your healthcare planning team (all 500 of them) have a credibility problem with how you plan to pay for all this, a credibility problem big-time, as they say nowadays.

As is well known by now, the American Medical Association and other medical societies around the country have been urging action for years by policymakers on the significant problem of providing care for the uninsured, about six million of them in California alone. And we have been supporting the universality of access, with affordable quality medical care.

There are many good, and some not so good, provisions in the various health system reform proposals now before the Congress. But let us not forget one reality: Someone, somewhere, has to pay the bill, and the American people will want to see a clear path ahead if some of the reform notions are to gain widespread acceptance.

The suggestion that the enormous expansion of healthcare programs can be financed by squeezing the fat and the fraud out of the present system stretches economic logic, no matter how many computer models are used to simulate savings. What is more troublesome is that the aging of the population, emerging medical technology and new drugs, combined with normal increases, seem to be ignored or minimized as they don't have a direct bearing on the increased cost of medical care delivery.

While the public opinion polls show support for health system reform, they also show support for health system reform, they also show a deep-seated suspicion of the Clinton dollar projections to finance his plan. Could it be that the Clinton administration, one of the most powerful special interests in the country, is deliberately choosing vagueness or worse over reasonableness in projecting the costs of the reform — sort of a "pass it at any price" approach.

As the nation embarks on a vigorous debate on the merits of the Clinton reform and other competing proposals, it seems to us that the projected price tags placed on each provision, each change, should be accurately and honestly presented to the people and the Congress. Of course, they will be estimates, but the financing of the program is critical, and the estimates are a vital part of the debate. *Now* is the time to consider the cost, as well as other important aspects of the proposals, not after a law is passed.

20th Annual USACOM Medical Student Research Day

University of South Alabama College of Medicine

Medical students and selected undergraduate students were given the opportunity to spend 8 weeks during the summer of 1993 performing biomedical research under the tutelage of a College of Medicine faculty member. Students communicated their research findings to the College of Medicine on Research Day (August 13) as either oral or poster presentations. Featured speaker at Research Day was Ernest M. Wright, Ph.D., Professor and Chairman of the Department of Physiology of the University of California at Los Angeles, who gave the plenary lecture "Molecular genetics of intestinal sugar absorption: bench to bedside." The following abstracts were submitted by the students as formal reports of their research findings. Student research was supported by NIH Training Grant 5T35 HL007509-13, Juvenile Diabetes Foundation International Summer Student Program Grant 593010, Cancer Education Program Training Grant 2R25Ca40021-09, Comprehensive Sickle Cell Center Grant 2P60 HL38639-06, and the University of South Alabama College of Medicine.

Continued from November '93

Detection of Okadaic Acid, the Major Toxin Associated with Diarrhetic Shellfish Poisoning (DSP), in Methanol Extracts of Whole Oysters

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Marine biotoxins represent a significant and expanding threat to human health throughout the world. Although rarely life threatening, diarrhetic shellfish poisoning (DSP) is considered by some to be the most serious and globally widespread phytoplankton-related seafood illness. The major toxins associated with DSP, okadaic acid and dinophysistoxin-1, have recently been demonstrated to have potent and specific inhibitory activity against certain serine/threonine protein phosphatases. To further our understanding of the relationship between DSP-toxins and protein phosphatase inhibition we conducted correlative studies with okadaic acid and highly purified protein phosphatases as well as the phosphatases contained in a crude whole homogenate of PC12 cells. These studies indicate that okadaic acid, at concentrations between 1.0 nM and 100 nM, completely inhibits the activity of both highly purified protein phosphatases and the divalent cation independent protein phosphatases contained in a crude PC12 cell homogenate. Thus we wondered if this unique pharmacology could be exploited to detect the presence of okadaic acid in seafood. To test this hypothesis we added okadaic acid at concentrations ranging from 0.02 to 2.0 μg/g to commercially obtained oyster samples. The homogenates were then extracted with 80% methanol and aliquoted for use in the phosphatase bioassay. These studies indicate that the phosphatase bioassay is capable of detecting okadaic acid in whole oyster extracts. Oysters containing 0.1 to 2.0 μg/g of okadaic acid were easily detected using highly purified enzymes while the detection of toxic levels of okadaic acid using phosphatases from a crude PC12 homogenate was found to be less effective.

Characterization of cDNA Clones and the RNA Encoding the Rat Liver Mitochondrial Citrate Transport Protein

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The citrate transport protein (CTP) is located within the mitochondrial inner membrane where it is responsible for the efflux of citrate via a citrate/malate exchange. In the liver, citrate serves as the carbon source for triacylglycerol and sterol biosyntheses. We have previously demonstrated that in type I diabetes mellitus (i.e., insulin-dependent diabetes) the function of the CTP is altered and that this alteration can be reversed by insulin therapy. With this background in mind, studies have been initiated to determine the molecular mechanism(s) responsible for CTP regulation. Since

preliminary data have indicated the possibility that more than one CTP gene may exist, we have sought to characterize both the cDNA and the RNA that encode the CTP. At the level of the cDNA, 24 putative CTP clones previously isolated from a rat liver cDNA library have been analyzed by the polymerase chain reaction (PCR) in order to determine the insert size as well as both the existence and location of known CTP sequences within a given clone. Our results indicate that the inserts range in size from 0.8-2.3 kb and can be characterized as two different populations. One population of clones contains primer binding sites similar to that observed with a previously sequenced 1.9 kb CTP cDNA clone known to encode the entire open reading frame of the mature CTP. A second group of clones appears to have a different sequence and may correspond to expression of a second CTP gene. At the level of the RNA, Northern Blot analyses, carried out using a PCR-amplified 584-bp CTP cDNA probe (which encodes two-thirds of the CTP open reading frame), indicated hybridization primarily with a 2.1 kb RNA species. A second hybridizing species is observed at 4.0 kb. These results suggest that a second gene may be expressed in rat liver at low abundance. In summary, the PCR-mapping of putative CTP cDNA clones and a characterization of the resulting RNA transcripts provide an important foundation for future investigations into the expression of CTP gene(s) and the effect of diabetes on this expression.

Cigarette Smoke Increases Pericellular Permeability in Type II Alveolar Epithelial Cells by Oxidant Injury

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Cigarette smoke exposure, *in vivo*, increases permeability in the respiratory epithelium. However, the mechanism by which this phenomenon occurs is not established. To determine the *in vitro* effect of cigarette smoke on permeability in the respiratory epithelium, confluent monolayers of alveolar epithelial cells were grown on collagen coated polycarbonate filters and exposed to cigarette smoke conditioned medium. Epithelial permeability, measured by [^{14}C] mannitol flux, increased in a dose dependent manner after exposure to cigarette smoke. Permeability increased in monolayers exposed to cigarette smoke on the basolateral side only. But in monolayers exposed on the apical side only, permeability was not changed. Increased mannitol flux was associated with a decrease in electrical resistance, and some evidence of irreversible cell injury. Increased mannitol permeability after cigarette smoke exposure was also associated with marked changes in the actin cytoskeleton. Cigarette smoke contains reactive oxidant species including H_2O_2 and O_2^-. To test the hypothesis that cigarette smoke conditioned medium increases permeability by oxidant injury, cells were exposed to cigarette smoke conditioned medium plus the antioxidants catalase (10,000 Units/ml) and superoxide dismutase (1000 Units/ml). The antioxidants almost completely prevented the increases in permeability suggesting that the changes seen after exposure to cigarette smoke is due to oxidant mediated injury to alveolar epithelial cells.

The Frequency and Motivational Factors of Affiliative Behaviors in Infant Squirrel Monkeys

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It has been long established that squirrel monkeys, like most other primates, use non-aggressive interactions such as grooming, sniffing, or touching to form and strengthen social bonds. In captivity, these behaviors persist allowing for the convenient study of the frequency of these actions as well as the factors affecting their initiation. By studying these aspects of basic social behaviors, it may be possible to gain insight into more complex affiliative interactions such as allomaternal care, a behavior defined as care given to an infant by an animal other than its dam. Ten infant squirrel monkeys were observed for 15 minute periods three times per week during the time of the establishment of their interactive skills (week 1-8 of life). Affiliative behaviors initiated by and directed towards the infants were noted and the ages, sex, and kinship of all animals involved in each point action were examined by statistical analysis. There was a significant decrease in the time that the infants spent dorsal on their dams as the infants advanced in age. The data revealed that proximity with related animals was primarily initiated by the dam. There was a trend for non-kin monkeys in the four to six year old age group to be involved in the initiation of proximity or contact with the infant. Future studies will use this preliminary data as a basis for determining the cause and purpose of allomaternal behavior.

A_2 Adenosine Receptor (A_2AR) Desensitization in the Pulmonary Circulation

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Desensitization of the A_2AR has been previously observed in the DDT cell line to occur in 1 hr. As previously reported (FASEB J. 7:A651, 1993), the adenosine agonist, NECA (10μM), resulted in a 50% inhibition of the vasoconstrictor response seen in the isolated rat lung model when constricted with a 3% 0_2 gas. This response is at least in part mediated via the A_2AR. Thus we hypothesized that prolonged exposure of the A_2AR to the adenosine agonist, NECA, would result in desensitization as characterized by the attenuation of NECA-induced vasodilation. In this study, lungs (n = 14) were sequentially challenged × 3 with a 3% 0_2 gas mixture for 10 min initially and 25 min for subsequent hypoxic pressor responses (HPR). All data is expressed as mean ± SEM and the Ppa in cmH_2O. NECA was administered to the perfusate reservoir during the peak of the 2nd HPR resulting in a decrease in Ppa of 12.7 ± 0.9. At the plateau of the 3rd HPR, NECA was again administered as previously described resulting in only a 0.17 ± 0.17 decrease in Ppa. In additional studies, lungs were pretreated with NECA (10μM), then subsequently were administered either adenosine (7.5 mM infused into the P.A., n = 3), the β_2 agonist, isoproterenol (1μM, n = 3), or the c-GMP inhibitable, c-AMP PDE inhibitor, indolidan (1μM, n = 3) into the reservoir during the plateau of the 4th HPR. The effect of adenosine infusion (7.5μM) in the lungs not receiving NECA was also assessed. In adenosine control lungs, the Ppa decreased 15.4 ± 1.6 as compared to 2.3 ± 1 in lungs pretreated with NECA. In contrast, lungs tolerant to NECA resulted in an 87.0% and 59.7% decrease in the HPR following administration of isoproterenol and indolidan, respectively. Comparatively, lungs (n = 6) pretreated with the A_{2a} agonist, CGS-21680, did not alter NECA-induced vasodilation as compared to NECA alone. Thus we conclude desensitization of the A_2AR in rat pulmonary circulation does occur, is specific, and is not related to the A_{2a} receptor.

Screening a *Rickettsia Prowazekii* Lambda ZAP II Clone Bank for the *rpoB* Gene

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Rickettsia prowazekii is an obligate, intracellular parasitic bacterium that exhibits a slow generation time (8-20 hours) as compared to a free living procaryote such as *Escherichia coli* (20-60 minutes). Such growth characteristics offer the promise of prominent genetic regulatory systems. A key enzyme involved in procaryotic gene expression is the DNA dependent RNA polymerase which is composed of α, β, β', and σ subunits. Recently, a portion of the rickettsial *rpoB* gene, which codes for the β subunit was isolated. The aim of this study was to isolate the entire *rpoB* gene. A Lambda Zap II R. *prowazekii* clone bank was screened for *rpoB* using the previously obtained *rpoB* DNA fragment as a hybridization probe. Approximately 150,000 plaques were screened. Twenty-eight plaques positive for *rpoB* were identified. Further screening identified three plaques that hybridized strongly to the *rpoB* probe. These recombinant bacteriophage were rescued as plasmids and analyzed by Southern hybridization, revealing two plasmids that continued to hybridize to the probe under high stringency. Nucleotide sequence obtained using a degenerate oligonucleotide primer specific for *rpoB* revealed that these two recombinant plasmids contain *rpoB* sequences. Restriction digests suggested that these clones contain additional segments of the R. *prowazekii rpoB* gene. Nucleotide sequence of those clones is being obtained to confirm the presence of a complete coding sequence. Characterization of rickettsial *rpoB* will increase our understanding of gene expression in these obligate intracellular parasites.

Role of Adenosine Receptors in Modulating Inotropic Responsiveness in Newborn Rabbit Myocardium

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Adenosine receptors play a role in modulating contractile responses in myocardial tissue. Adenosine receptors are coupled to adenylate cyclase by $G_i(A_1)$ or $G_s(A_2)$. We postulated that populations of the two receptor types would change developmentally. To study this, right ventricular papillary muscles were isolated from newborn and adult rabbit hearts. Papillary muscles were attached to force transducers and submerged in oxygenated Krebs buffer at 30^0C. Muscles were stimulated with a duration of 3 msec, frequency of 0.5 hZ, and a voltage ten percent above the threshold. Isoproterenol dose responses (.3 nM to 100 nM) were performed with and without the presence of 30 μM adenosine and 10 μM EHNA, an adenosine deaminase inhibitor. Resting tension (RT), developed tension (DT), time to peak tension (TPT), time for 90% relaxation (90% REL), and the positive and negative maximal rate of change in tension (+ and −dT/dt) were

measured. In newborns, the maximal +dT/dt response to isoproterenol was attenuated by 55% and −dT/dt was attenuated by 48%. In contrast, adults showed only a 23% attenuated response for the +dT/dt and a 10% potentiated response for the −dT/dt. To further characterize these receptor populations, preliminary studies have begun in adult muscles using CGS 21680, an A_2 receptor agonist, and Rolipram, a selective phosphodiesterase inhibitor. 10 μM CGS 21680 alone produced a 13% potentiation of +dT/dt and 37% attenuation of −dT/dt. When 1 μM Rolipram was added prior to adenosine, +dT/dt showed a 4% attenuation and the −dT/dt showed a 15% attenuation. These inotropic and lusitropic responses suggest that adenosine exerts a balanced effect on A_1 and A_2 receptors in adult muscles, but in newborn myocardium, A_1 receptor influences predominate.

Vascular Reactivity Following Burn Injury

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Burn injury damages microvasculature, resulting in changes in blood viscosity and flow, vasodilation and increased permeability to macromolecules. The exact mechanism of these effects remains unknown. However, it is known that these effects occur concurrently with increased plasma levels of catacholamines. This study investigated the possibility that burn injury impairs vascular reactivity to norepinephrine (NE). All experiments were performed using isogravimetric isolated rat hindquarters perfused at constant flow with oxygenated rat donor blood. Burn injury was induced by immersion of the preparation into 100° C water for 8 seconds, resulting in a full-thickness, 50% total body surface area injury. Data collected from arterial blood includes, hematocrits, serum proteins, and spectrophotometric serum hemoglobins. These values were used in calculation the capillary reflection coefficient, sigma (σ), using Wolf's correction factor to Maron's equation. Total resistance (Rt), was determined by arterial and venous pressure readings. Tissue water was evaluated using wet/dry mass ratios.

Group	σ_I	σ_{NE}	Rt_I	Rt_{NE}	$\%H_2O_{Skin}$
Control	.741	.537	4.95	16.88	64
Burn	.538*	.368*	4.66	12.81*	75*

*indicated T-test significance of < .06

Burn injury resulted in a significant decrease in sigma, indicating an increase in microvascular permeability to macromolecules. The response to NE as indicated by total resistance was significantly attenuated by burn injury. Skin tissue water was significantly higher in the burn group, consistent with burn induced edema formation.

Effect of Hemorrhage and Mechanical Ventilation on Tracheal Blood Flow in Adult Rabbits

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Long term ventilation of infants and adults in respiratory distress may result in necrosis and sloughing of the tracheal mucosa, a condition known as Necrotizing Tracheobronchitis. This condition has been associated with hemorrhagic shock as well as mechanical ventilation. To determine if intubation and ventilation compromise tracheal blood flow, radioactive microspheres were used to assess cardiac output and peripheral blood flow distribution during 2 hours of conventional mechanical ventilation (CMV) in adult rabbits. Average tracheal blood flow, as determined by the reference organ technique, increased from 0.15 ± 0.05 to 1.08 ± 0.28 ml/min/g after 2 hours on CMV (n = 4). The increased blood flow occurred primarily in the mucosal layer. Cardiac output was unchanged (597.1 ± 36.1 vs. 538.8 ± 56.4 ml/min). The effects of hemorrhage in addition to CMV on tracheal blood flow were also measured. Mild hemorrhage (12 ml/kg body weight) in 4 animals did not alter the response for tracheal blood flow or cardiac output (1.61 ± 0.21 ml/min/g and 460 ± 43.4 ml/min, respectively) when compared to CMV alone. One animal was hemorrhaged to 55 cmH_20 for 2 hours. Both tracheal blood flow and cardiac output were decreased (0.94 ml/min/g and 215 ml/min, respectively) in this animal. These data indicate two points: (1) Tracheal hyperemia occurred after intubation and may be related to mechanical irritation of the tracheal mucosa and subsequent release of local metabolic vasodilators. (2) Mild hemorrhage does not compromise tracheal blood flow.



Mrs. William Hall
A-MASA, President

Doctors — What does the Medical Auxiliary do for your spouses?

Well, that's kind of like asking what medicine does for me. Medicine is part of my life.

It invades our home life with telephone calls, emergencies, disrupted schedules, and last minute changes of plans.

It places us in the public eye, with an image to uphold, a reputation to maintain, and a responsibility to "give back" to the community.

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I've become educated about the problems of medical practice and how to deal with them. Conferences offered nationally and on the state level and publications help me know what we face as a family "partnership" and how I can help.

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Because, as a member your spouse will be an informed partner in medicine. Publications such as AMAA's *Facets*, and our own state AMASA newsletter will keep spouses updated on what is happening in medicine across our state. Medical family concerns, health topics, and timely issues are addressed at our three annual meetings. We provide a vehicle for your voice to be added to a unified voice; one which is making an impact on the legislative process affecting the medical profession, and subsequently the medical family.

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Linda Hall
AMASA President

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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhebdomyolysis with renal dysfunction secondery to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondery to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of prevastatin and fibretes should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine. Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Leboretory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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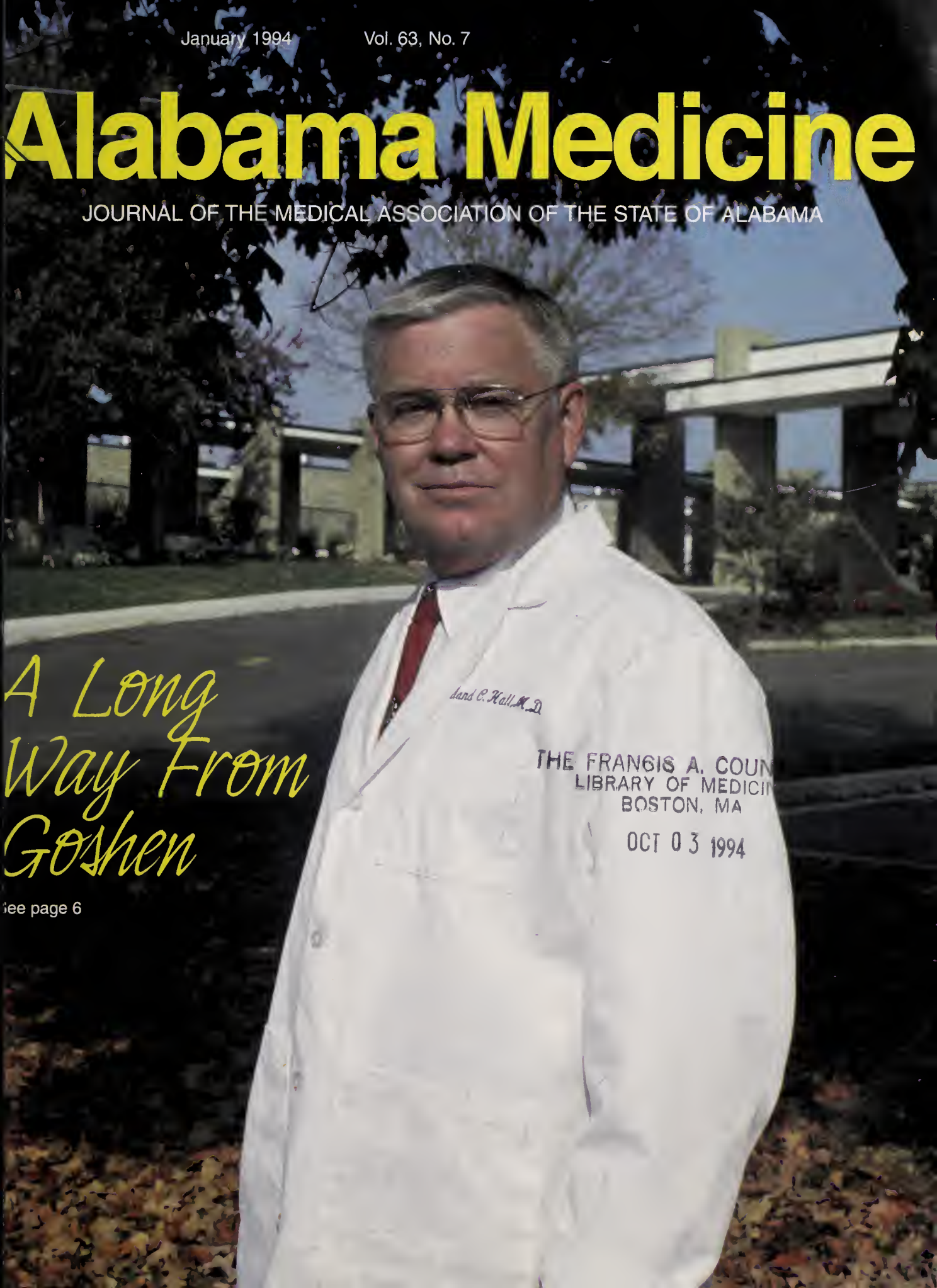
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Alabama Medicine

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A Long Way From Goshen

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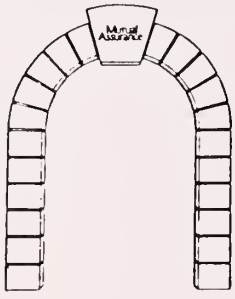
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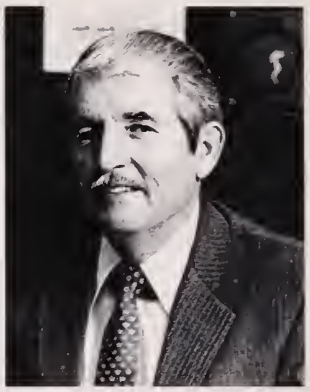
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

To the Shower, Doctor

"Who shall decide when doctors disagree?"

–Alexander Pope, 1732

A year ago, I shared the general anxiety current in the various branches and tributaries of organized medicine — when push came to shove in the health care reform movement, it was feared at the time, the opening strategy of the Clinton Administration would be to Balkanize the profession into contentious fragments. Divide & conquer would be the reformers' principal gambit, we all thought.

That fear was crystallized by Peter Morris, M.D., at the heading of his report last April on his 1992-93 presidential year to the College of Counselors and House of Delegates. Dr. Morris quoted Winston Churchill's warning of the dangerous folly of those countries tempted to appease Hitler as Europe moved toward the greatest war in human history. Churchill intoned:

"An appeaser is one who feeds a crocodile, hoping it will eat him last."

Since then we have seen many specialties, or at least their leaders, running off in all directions to feed the crocodile. MASA has just received an announcement from AMA President Joseph T. Painter, M.D., of a "Federation Study Consortium." The preamble to the prospectus on the study puts the situation in stark terms, confirming that last year's fears have become this year's reality:

"If there is one thing that is clear in today's environment, it is that nothing is clear. Medical organizations have proliferated and changed in size, scope and complexity as medicine itself has become more technologically sophisticated; physicians have become a more heterogenous group along demographic, practice and attitudinal lines, and the environment has become more and more intense, dynamic and hostile.

"There is a pervasive undercurrent of concern about how 'organized medicine' is no longer very organized and how it is a sitting duck for the divide and conquer strategy that many believe is being employed against the profession."

Of all the reform bills now in Congress, there isn't one that hasn't won the allegiance of some medical specialty or subspecialty — all the way from single-pay to what has been called pay & pray and even no-pay.

Obviously medicine's voice has become a tower of Babel in Washington.

How did we, and the nation, get to this point? I think every physician would benefit at this confusing juncture with a good, cold shower. And I know of no better showermaster than Edward R. Annis, MD, the 1994 Jerome Cochran lecturer at the annual meeting. His recently published book on the subject, *Code Blue*, will clear your head of the current noise and confusion about as well as anything I know.

Dr. Annis is best remembered for his famous Madison Square Garden speech of a generation ago when he gave the American physicians' response to President John F. Kennedy's speech the night before in weak support of what was to become Medicare.

Kennedy plainly did not have his heart in the speech. The following night Dr. Annis, speaking amid the debris from the staged rally for Kennedy, prophetically warned of the cost spiral to come. Physicians themselves would profit by passage, he said; physician income would rise, not fall, if Medicare became law. But the nation would suffer by the wholly unreal-

istic expectations created by politicians and by the years of budget-busting, which have followed as surely as night the day.

Other historians have confirmed that President Kennedy feared this and had no real stomach for the Medicare fight. It was left for Kennedy's successor, Lyndon Johnson, to ramrod Medicare through Congress as a putative memorial to the fallen leader.

AMA headquarters received 42,000 letters in response to Dr. Annis' speech. Shortly afterward, he was virtually drafted as President of the AMA. He has remained an outspoken proponent of the free market system in health care through the years; he might fairly be called an unreconstructed rebel in the ranks of organized medicine, which has generally shifted ground from the right to a little bit left of center by the standards of the 1960s , whereas Dr. Annis' philosophical position seems to be pretty close to what it was 30 years ago.

He defends the present health care system in virtually all its aspects. For example, he argues, as has been argued in *Alabama Medicine* in recent years, that it is demagogic for the media and politicians to berate the rising percentage of the GDP that goes to health care as if it were a total loss. Dr. Annis argues, as this magazine has, that the health care industry contributes 15% or so to the national economy, hiring more people than any other industry except the Defense Department. As I have commented in this column previously, if the automobile industry is a plus for the American economy — and who doubts that it is ? — certainly the vast health care industry is a greater one.

He points out the extraordinary burdens this country has in health care that are not approached by other western nations — AIDS, the drug epidemic , crime, teenage pregnancy, and the rest, coupled with a soft-hearted government philosophy that condones behavior that other nations would not tolerate. All these factors add billions to our health care bill. And the government has itself added to the problem:

"If an individual is to consume, and another is to produce that which is consumed, and if a third party is called upon to pay the second party for the consumption of the first, then it should be obvious that the third party must have some say over consumption or else demand will outstrip its ability to pay. You simply cannot hand out blank checks drawn on the taxpayers' account and expect that responsible trade will take place. Thus, in every socialist system, government has resorted to price controls and arbitrary rationing even when the means of production are left in private hands. In the case of Medicare — which was designed on socialistic principles — government has attempted to impose rationing by regulating the providers of health care, largely unbeknownst to the consumers."

Congressional supporters of Medicare, in common with Clinton administration supporters of their brand of health care reform, offer forecasts to predict how easily affordable it would be and how over-utilization dangers cited by Dr. Annis and others were scaremongering inventions to defeat passage. History has shown that the U.S. government is notoriously inaccurate in all cost projections but in none more so in health care.

Code Blue offers a wealth of information and argument in defense of the present system and much of it is persuasive. Two areas in which I think Dr. Annis is on shaky ground however are these: he paints entirely too rosy a picture of the present environment and he has an inordinate fondness for finding villains. The decay of the public school system, for example, can be laid at the feet of John Dewey; the malefactions of the media at the feet of old Horace Greeley; and Medicare and the present reform movement at the doorstep of England's Fabians and early native radicals in this country.

And, all along, I thought Dr. Spock was the culprit. The best rejoinder to Dr. Annis, however, is Dr. Annis (pg. 180): "... the problem arises from our penchant for blaming others for every misfortune that befalls us, even when the occurrence is an act of God."

Such minor lapses aside, *Code Blue* is a provocative book that should be read by every physician if for no other reason than to use in answering those incessant boors who are forever knocking your profession and challenging your defense of it. There is ammo aplenty here.

PRESIDENT'S PAGE



James E. West, M.D.
President, MASA

First, Do No Harm

The following remarks were made by Dr. West at the recent MASA Washington visit with the state's congressional delegation. Present were both Senators, Congressmen, Alabama Physicians and their wives. Dr. West's short address, the first ever by an Association President at this annual event, was well received.

–Ed

Good Evening Ladies and Gentlemen!

On behalf of MASA staff, officers, and members of the Board of Censors I want to thank my colleagues and their guests, members of the Alabama Congressional Delegation, their guests and staff for coming to this most important meeting.

I especially want to thank Dicky Whitaker and Mark Jackson for their leadership in putting this together and for their leadership throughout the year.

I also want to thank Lon Conner, Executive Director, George Oetting, Director of CME, and Vic McLean, Director of Public Relations, for their assistance as we are dealing with Health Reform.

The issue before us is Health Systems Reform! The most important issue facing physicians and our patients since the mid 1960's.

The Alabama Congressional Delegation is facing many important issues...Health Reform is only one!

However, this one issue may be more important to the American People than all the other issues combined.

I sense that we may be on the verge of potentially setting up the greatest Entitlement Program this country has ever had!

I do not envy our Congressmen, who by virtue of their position in government, must make tough decisions and then finally to cast a vote. For good or bad, we will live with it well into the next century.

Yours is an awesome responsibility! And we thank you for accepting this decision making role!

Ours is a Representative Democracy; and therefore, we have ample reason to be here. Our representatives in Congress need to know all about this issue, and it's our responsibility to tell them what we know and think so that they can make informed decisions.

No one knows better the impact of the proposals before Congress than physicians for we are: Providers of care, small business, and patients.

903 billion dollars is a lot of money, and that's an estimate of what was spent in the United States for Health Care in 1993. Some say "that's too much!" And some have said their is a Health Care Crisis!

There is no Crisis in Health Care! Today we can cure more, palliate better what we cannot cure, and we can prevent more disease. In addition the life span has increased significantly so that there is an ever growing population of people over sixty-five.

We in the U.S. enjoy the best medical care of anywhere in the world...and we can deliver it without a waiting list!

You and I are providing that care now! We just aren't getting paid for it 30% of the time!

In fact, if we develop a new system as presently proposed, we may actually deny timely care to more people than are currently affected because there will have to be a limitation of care or "RATIONING" so that we can afford The New System.

Our System of Health Care does need some change...But it does not need to be Reformed.

The AMA in 1990 recognized that changes were needed and we developed Health Access America—A Plan for Providing Health Care for all Americans!

This Plan was developed from the bottom up by involving Providers at the grass roots level, then by adding input from the Hospital industry, Insurance industry, Accountants, Economists, etc...People who know about Health Care and Health Care Delivery!

The proposals now before Congress began at the top and have not benefitted from the input of people who Really know Health Care Delivery!

Not all doctors in this room may agree with what I am saying, and not all doctors may agree with MASA or all of the AMA Plan. We come from different backgrounds and environments, and we have different ideas. But we all agree that Health Access America is the only well thought out Reasonable Plan. And we all embrace the Principles embodied in the Plan!

Choice, Quality, Simplicity, Savings, Security, and

Responsibility are principles ascribed to the Clinton Plan. But when you read the fine print of the Clinton Plan and the others, you find that Choice may be lost or limited and that Savings may not be there at all!

There is not at this time a good Proposal before Congress. There is some good in some of them, but there is lots that's bad in all of them!

They all spell C-O-N-T-R-O-L, increased Bureaucracy, loss of Freedom by states, patients, and doctors, and increased Costs.

THE FEDERAL GOVERNMENT JUST CANNOT BE ALL THINGS TO ALL PEOPLE!

Perhaps it's time to face reality and to be honest with ourselves and the American People, and not try to Reform the entire System.

WE JUST CAN'T PROVIDE MORE CARE TO MORE PEOPLE AT LESS COST!!

85% of Americans are happy with their care and their coverage, and the rate of growth in Medical Care Cost is already decreasing. The System is correcting itself!

It it not time to focus on the 14-15% who are caught in between Medicaid and Medicare and private insurance?

We believe it is time to concentrate our Federal Efforts at that level and perhaps to study the need for other reforms, do pilot studies etc. to see what is needed and what works!

In closing I ask our Senators and Representatives to determine whether or not the proposed bills are reasonable!

We feel as a minimum these bills should provide for:

a. Extended coverage for all Americans
b. Freedom of choice
c. Real Antitrust relief
d. Meaningful Tort Reform
e. Reasonable cost containment

There needs to be defined a Basic Benefit Package.

We believe that "quality" should be determined by and monitored by physicians.

Since 85% of Americans are satisfied with their care, let's go back to square one and concern ourselves with the uninsured and the medically indigent!

If additional funding is needed it should be from a Broad Base and should not come from stealing from Medicaid or Medicare!

Members of Congress: Please listen to us and to the AMA who is ever present in Washington! Call upon either of us at anytime!

We are a self interest group but primarily we see ourselves as advocates for our patients and for the system that best serves their needs.

Our patients are your constituents as well so let's together serve them to the best of our ability.

Thank all of you for being here and for listening to what I had to say.

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Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatric. It may have activity as an aphrodisiac.

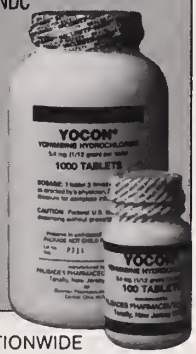
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

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References:

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A Long Way from Goshen

William H. McDonald

If you ask Garland C. Hall, Jr., MD, the 1994-95 President of MASA, whether he feels jinxed that his presidential year coincides with what may be a radical transformation of the health care system, he might answer with a parable. This parable, for example:

One summer his Gadsden high school baseball team condescended to play a ragtag team of misfits, rejects and outcasts — those who had been adjudged insufficiently talented to make the regular team.

It would have been a mismatch but for one thing: the ragamuffins were coached by Garland's father — a man who had been an undaunted football walk-on at the University of Alabama in 1926 standing five-seven and weighing 135 pounds; a man who told a Hall family reunion a year before his death that he wanted to be remembered as a lifetime coach (although he had also been a school teacher and principal).

Coach Hall's pariahs had a one-run lead but the high school regulars were at bat with runners on second and third. Garland was on deck. His father stopped the game, instructing his pitcher to walk the man ahead of his son. Thus, with the winning run on base, glorious victory was within Garland's grasp.

But fate was not smiling. He struck out. His father's ragamuffins won.

Afterwards, when people gave Coach Hall a hard time for sacrificing his own son just to win, he would say: " I didn't sacrifice him. I gave him a chance to be a hero or a goat...."

And how does this parable apply to the fateful year for American medicine? With his characteristically enigmatic grin, Dr. Hall likely wouldn't spell it out. Maybe he would perceive that organized medicine has the historic opportunity to be the hero or the goat this year. And, with the still keenly remembered pain of his own goathood long ago in Gadsden, and raising that pain by many orders of magnitude in the case of health care reform, perhaps this: if organized medicine does not present a heroic stature this year, The Year of the Goat could haunt and hobble American health care well into the 21st Century.

If Nostradamus had been a stand-up comedian, his Oracles might have sounded somewhat like those of Dr. Hall. He doesn't like to be pinned down, and he doesn't cotton to giving or receiving long, convoluted answers.

Ask him, for example, where he grew up and he will retort, "Nowhere yet." Ask him where he met Phyllis, his lovely wife of 37 years, and he will answer, deadpan, without elaboration unless pressed, "at an autopsy."

He is notorious for cryptic one-liners. Ask him for example, what is going to happen in Washington this year and he may say (in fact, *has* said): "American health care is at the crossroads. We will have either health care rationing or health care rationalization."

After the initial laughter at such a vintage *bon mot* as this, you wonder: What exactly does this epigram mean? He may be pulling your leg; then again, this may be a pithy, trenchant analysis of the nation's peril.

Look at his either-or statement again. Given his fondness for puns, its meaning would seem to turn on rationalization, which in this context could have at least two meanings: (1) the act of justifying or excusing; or (2) the process of making the system rational. But if you settle on one or the other, you're not much closer to a translation. Even so, either interpretation effectively capsules thousands of empty words we have heard on the subject, and will continue to hear.

Another possibility is that it is simply his way of saying he is tired of all the bootless speculation about what will transpire when plainly no one, at this point, has the foggiest idea. Thus, the throwaway line may be deliberately offputting, as if to say, "How the hell should I know?"

It is just possible that a man still agonized by the memory of that goat-hero chance he blew in a summer long ago refuses to swing at a sucker ball; his father may be up there somewhere watching.

Having observed Dr. Hall in monthly Board of Censors meetings for the past 11 years, I have concluded that some of his sardonic comments amount to gamesmanship, although it is not always clear what the game is. Sometimes it is obviously his way of gently protesting that a discussion has droned on long enough. If he is asked to elaborate, his one-liners are revealed as apt distillations of the subject at hand, although the meaning may be veiled by metaphor or

pun. The following exchange should illustrate.

Question: "Dr. Hall, you were in the service, were you not?"

Answer: "Yes. I served in the Army on my lunch hour."

What would seem an utterly facetious answer is almost literally precise, as it turns out. But he won't explain unless you take the bait and ask. If brevity is the soul of wit, Dr. Hall has mastered the art form.

Garland Hall was born in Goshen, Alabama, Pike County, in the Depression year of 1931. His parents were teachers in the public schools. When Garland was 3 years old, they moved a short distance to Ariton, near Ozark, in adjoining Dale county. (When his mother retired from teaching after 45 years, she had not missed a single day, of which Dr. Hall says: "If I match her record, I've got to practice without missing a day until I am 92.")

In 1938 they were again transferred, to Vincent in Shelby County. And it was here, Dr. Hall believes today, that his interest in medicine was born. Dr. Carl Embry was the family doctor, the only doctor in that small town, with all that this role implied in community esteem. In addition, Dr. Embry gave young Garland his first puppy, thereby convincing the impressionable young boy that there could be no finer life than that of a physician. A man with puppies to spare obviously had the world in a jug and the stopper in his hand.

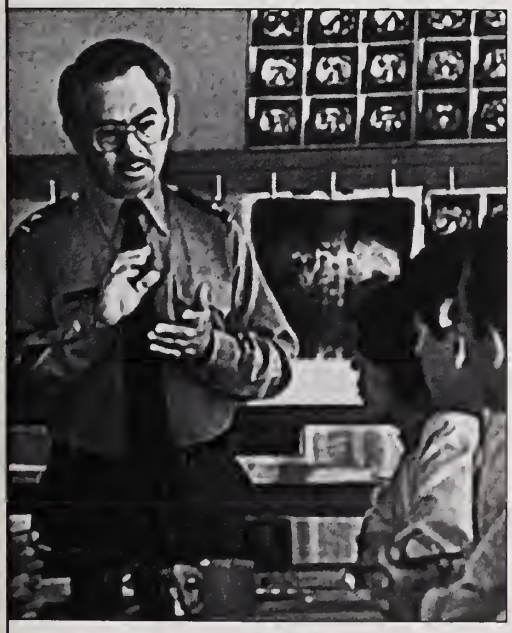
The family's final move was to Gadsden. Having participated in all sports, Garland graduated from Gadsden High School in 1950 and was off to Tuscaloosa, where he earned his B.S. in 1954. After graduating from the Medical College of Alabama with his M.D. degree in 1959, he served his internship at Carraway, which was to be followed by his curious military service and family practice residency in, of all places, Bangor, Maine.

And thereby hangs a tale.

The Army ordered him to a recruiting station in Bangor, where he had so little to do he can say with almost literal accuracy, "I was in the Army on my lunch hour." (Later, the Army was to send out a directive with the case study of Dr. Hall as a horrible example of how things would not be done in the future.)

As it happened, a 250-bed hospital, Eastern Maine General, was located in Bangor. As it also happened, a previous medical director at the hospital had fallen into disfavor with the town physicians because of his use of problem-oriented data bases, and he had been

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given his walking papers. The fired medical director thereupon wrote the physicians he had recruited as residents, informing them of his departure, and suggesting that they might want to make other plans. They did. The result was a large hospital with no house staff.

Like nature, Dr. Hall abhors vacuums. Although still serving the Army on his lunch hour, he applied for a job with the new medical director, who had trained at Harvard, but was told there were no funds available to pay him. Dr. Hall said that he would work for nothing, and that his real desire was to see patients and to be involved in patient care.

That was an offer the medical director could not refuse. So, for two years, Dr. Hall was the only resident, simultaneously serving the Army's minimal needs. At Eastern Maine he had his pick of what he wanted to do; he did chiefly surgery and obstetrics.

After all these years, Dr. and Mrs. Hall still return to Bangor a couple of times a year; they were there after last Christmas.

Since he had attended medical school on a state scholarship, he had to return to Alabama for a year. To establish a base from which to operate, he opted for a year of surgery at Carraway in the conviction that this would prepare him for rural practice.

He picked Moulton, Lawrence County, from a map: "I had never been there before but I liked where it was on the map. I had started to go into practice with a classmate of mine in Muscle Shoals. Then I got a call from Moulton. I drove up from Cullman on 157 and as I looked over that valley, it looked like the promised land to me."

He became the third doctor in Moulton. There are 10 today. The population then was 1,710 and is about 4,000 today. Dr. Hall is utterly convinced that the world is the young physician's oyster, if he or she follows this simple rule: "You can go where you want to and have a good life if you take care of people."

But it also helps, as Dr. Hall is quick to add, to have had the support and companionship of a wife such as his, the scintillating Phyllis. As a dental hygienist student from Jacksonville, Florida, she and several of her classmates were required, in their rotations, to observe an autopsy. Medical Student Garland Hall, as fate would have it, was doing one when the group showed up. Afterwards, he gallantly squired them all home. He and Phyllis had their first date the following Monday — a seven hour date. They played miniature golf, ate pizza and went to a movie.

They were married three weeks later, a courtship so short that its length was concealed from Dr. Hall's straight-laced father until his death. He would have been properly outraged.

Of the five children of Dr. and Mrs. Hall, only one followed his father's profession. Robert B. Hall, M.D., is in family practice in Moulton, but independently of his father. Garland C. Hall III is an attorney in Decatur; Kathryn Hall Taylor is a clinical psychologist in Tennessee; Lee Ann is a student at the University of North Alabama; and Allen is a history major at the University of Alabama.

"None of the doctors younger than I am have kids in medicine; doctors older than me have one or more kids in medicine. Something has changed. One thing that has changed is that too many doctors are saying they wouldn't go into medicine if they had it all to do over again, and wouldn't let their children follow them. If that's their attitude, they went into medicine for the wrong reasons. We are turning out entirely too many doctors and not enough physicians. I would do it all over again tomorrow if they would let me."

Like other physicians who have been significantly involved in organized medicine, Dr. Hall has the benefit of an inside view of the waves of change sweeping over private practice. Since 1983 he has served on the Board of Censors, the Board of Medical Examiners, and the State Committee of Public Health. He has also served as a member and is the present Chairman of the Board of the Alabama Quality Assurance Foundation; on the Advisory Board of the University of Alabama School of Medicine; as Chief of Staff and on the Board of Directors of the Lawrence County Hospital, Moulton; and as President of the Lawrence County Medical Society.

From the various vantage point these positions have provided, he says:

"I think private care is going to be reshaped, whatever happens in Washington. The reshaping has already begun. We will all have to belong to some big plan to practice. My greatest fear is a single-payer plan. I know there are some doctors — the Board of Regents of the American College of Surgeons, for example — who say it won't be so bad. But I think it will have disastrous effects on patient care.

"Whatever happens, the doctor has no conscientious choice but to be the advocate of his patients. If we all continue to do that, the economic rewards will follow. If I had to guess what it will be like a year or so from now, I might predict that everything will be at the Medicare reimbursement level. It makes no sense at all to me that the country would even consider tearing up the health care of the 85% of Americans who are reasonably happy with what they have just to provide for the small remainder.

"There are a few entrepreneurial doctors who game the system and charge outrageously. There are some good old Alabama boys doing this, with Alabama accents. We all have to pay for their behavior. If single-payer brought them down, I guess it would help me tote the cross .

"There are so many things wrongheaded now about the effects of third-party payers on health care that I

dread to contemplate what the future might hold. Take one example: under DRGs, a hospital's successful treatment of a heart attack penalizes the hospital financially because there are more services and higher costs for the patient who recovers. On the other hand, if the patient dies, the hospital makes money. We've seen any number of examples of this reverse incentive. It distorts the whole process of health care. I don't even want to think about what a mess it could be with even greater intrusion from the public or the private sectors."

Reflect for a moment on the changes in the art & science of medicine as well in socioeconomics of health care over just one lifetime, that of Dr. Hall:

When he was born in Goshen, Alabama, in 1931, almost none of the modern drugs and technology were available. Some Alabama physicians barely survived economically, and often accepted barter in lieu of fees.

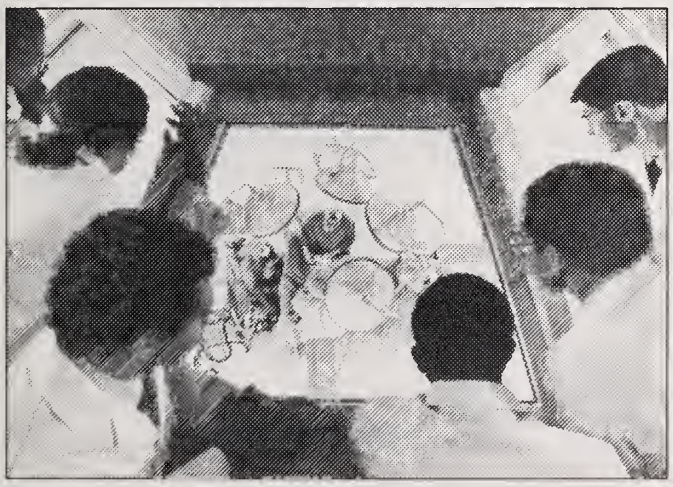
For all practical purposes, third-party payers did not exist. Infectious disease was rampant; few of the great killers and cripplers had been tamed.

It would be a dozen years before an American president would even consider national health insurance. Medicine was still more art than science; the kindly old family doctor enshrined in the public consciousness was alive and well, although his armamentarian was woefully limited compared to that of today's physician.

To be sure, medicine was more personal than today and the physician enjoyed unquestioned community respect and admiration. Anyone who even thought of suing a doctor would have been ridden out of town on a rail by the physician's outraged townspeople.

Every age experiences nostalgia for the simplicity of the past, which is glorified and haloed by the cosmetics of memory. But to Dr. Hall the Golden Age of Medicine, all the tribulations notwithstanding, is now. He accepts change and the threat of change as challenges, not ruin, believing as he does that physicians should cultivate a kind of clinical tunnel vision that always focuses first on patient care, whatever eventuates.

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When physicians feel that a problem with alcohol or other drugs may be manifest in a colleague, that feeling is usually correct. Unless some type of intervention is considered and acted upon, the disease will always progress. The goal of an honest and caring intervention is to get the individual to accept an evaluation by experienced professionals.

The following case history is presented in an Alabama physician's own words. He wishes to remain anonymous. His story describes with feeling the dilemma of continued drinking despite adverse consequences, changing the office schedule to accommodate drinking, unsuccessful attempts to cut down, changes in physical appearance, and "shame and self-pity." His denial is evident even up to the moment of intervention.

After treatment and resolution of anger and resentment, renewed insight is revealed in his statement, "I truly believe that my intervention has given me a new and better way of living and has saved my life...." His successful story follows.

Gerald L. Summer, M.D.
Medical Director
Physicians Recovery Network

On the morning of 11/11/91 I awoke with my usual hangover — nausea, tremors, and sweats — no real headache, I just felt bad. I also felt guilty because I had been on call for our group the night before and had vowed (as I had done for the past few months) not to drink while on call. My progression to this stage of alcoholism had taken many years, but the disease process was moving rapidly now. In the past two years I had promised myself that I would only drink on Saturdays, then Fridays, then weekends, then nights I was not on call. I had changed my usual surgery day from Monday to Tuesday because the continuous weekend drinking made Mondays physically impossible to work in the OR. I had begun cancelling the last two to three patients on my afternoon schedule to begin drinking as soon as office hours ended. I knew it would be just a matter of time before I started drinking during or even before office hours. Even now I was having a couple of drinks before making weekend rounds.

Looking at my bloodshot eyes and red puffy face in the mirror I felt shame and self pity. I had watched myself become more and more isolated from family, friends, and colleagues, and preferred to stay alone so I could drink without having to hide or make excuses. I felt that as long as I still went to the office every day and didn't hurt a patient, that I would be O.K. until I could cut down on drinking. I took Bufferin, put in Visine and thought of excuses for my red face. Usually, if questioned, I blamed it on sunburn, but it had rained this weekend.

As I drove to the office I promised myself that I would not drink until Saturday and then only after sundown. When I arrived at work my office manager said a Dr. Summer with the Medical Association had called and wanted to talk with me. I had a sudden panicky fear because I had seen his picture in the *Journal* and knew who he was and what he did for MASA. Immediately, however, my denial of my own problem began working, and I rationalized that he probably needed my advice on how to handle some situation with another physician. On the phone he gave no hint of what he wanted but asked to come to my office that afternoon when we had finished seeing patients. All day I had a nagging fear that he might want to talk to me about *me*.

At 4:00 I sent my staff home and waited. Dr. Summer and Lon Conner arrived. I felt better because I had known our executive director, Mr. Conner, for several years while working on projects with MASA. At that point I was sure that they needed my help with something.

After we were introduced Dr. Summer's opening words were "I have reasons to believe that you have

a problem with alcohol.'' The sudden sinking fear was overwhelming. The rest of the meeting was fuzzy, but I remembered him asking me to have a 96-hour evaluation. If I complied with his request I would be protected from the Board of Medical Examiners. Otherwise, I would be subject to a full investigation by the Board and possible disciplinary action. After the meeting my fear gradually subsided and was replaced by a feeling of relief. The decision to get help had been taken out of my hands!!

Then I began to get angry because my denial and rationalization process told me I would have done this on my own if left alone. I needed someone to blame, but Dr. Summer said names of individuals providing information were confidential. Had a complaint come from a friend, a patient, a family member, a colleague, or an enemy? I suspected everyone, but Dr. Summer was the target for my resentment, which continued to grow even after my four-day evaluation ended with a diagnosis of alcoholism and a recommendation to seek treatment in a facility experienced in treating physicians — which I did.

I have now passed my second anniversary of sobriety. I attend regular meetings of a recovering professionals group and AA. The difference in my personal life is incredible, my medical practice did not suffer as I feared, and my colleagues, friends, and family have been totally supportive of my recovery. Even though I have had some major stresses in my life since leaving treatment, I have been able to deal with all of them without the need for chemicals.

In short, I have a new life which is infinitely better than when I was drinking. I am very grateful for the way I was treated by Dr. Summer and all of the other members of the Physicians Recovery Network. I hope that in the future insurance companies will pay for appropriate treatment.

I do know that it was several months after leaving treatment and returning to practice that I was able to give up my resentment because I continued to feel that I could have handled my own problem without any outside help. However, after looking at my situation with total honesty, I could finally admit that I would never have sought help for myself unless a severe disaster occurred, such as injuring a patient or someone else as a result of my drinking.

Help was forced on me out of caring rather than as a punishment or penalty. I truly believe that my intervention has given me a new and far better way of living and has *saved* my life as well as protecting the life and health of the patients under my care. I now have a healthy new way of dealing with fear, anger, guilt and shame and all the other negative emotions I had previously hidden with alcohol. I can run my medical practice instead of letting it run me, and I personally have a sense of peace and well-being that I never dreamed could be possible. Each day I can thank God for my new life and for the caring people who directed me to it.

This physician's success story is typical. When properly intervened upon, evaluated, and treated the great majority of physicians treated for all types of chemical dependency can return to the productive practice of medicine. MASA has a program to encourage early identification of the sick physician with a goal of rehabilitation. The Physicians Recovery Network was developed to assist physicians in Alabama who may be becoming impaired as a result of chemical dependency, mental or emotional disorders. A confidential call to 1-800-239-6272 or (205)261-2044 will begin the helping process.



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Disc Space Infection

*LeRoy F. Harris, M.D.**
Frank P. Haws, M.D.†

ABSTRACT

Disc space infection or discitis, an infection of the intervertebral disc with contiguous subchondral vertebral osteomyelitis, most frequently follows prior intervertebral disc surgery or arises by hematogenous dissemination. The majority of cases are located in the lumbosacral spine and are caused by staphylococci. Clinical findings include localized spinal pain and fever. The diagnosis is suggested by radiologic studies (plain x-ray, bone scan, CT scan and MR imaging) and confirmed by culturing blood or material obtained from the involved disc space. Treatment consists of antimicrobial therapy, spinal immobilization and surgical intervention in selected circumstances. Discitis is associated with a good prognosis but residual back pain, limited spinal mobility and neurologic deficit may occur.

DISC SPACE INFECTION

Disc space infection or discitis is an infection of the intervertebral disc with contiguous subchondral vertebral osteomyelitis. Although the condition is well delineated in children[1-3] and following disc surgery[4-6] only one large series[7] describes a general discussion of the infection in adults. Because the diagnosis of disc space infection often is delayed resulting in serious neurologic complications[8] and because discitis is not an infrequent infection in our experience, we feel it prudent to present our cases of disc space infection.

Materials and Methods

We reviewed the charts of all patients discharged from the three community hospitals in Huntsville, Alabama, with a diagnosis of disc space infection for the seven year period, 1985-1991, inclusive. Disc space infection was defined as a compatible clinical syndrome with characteristic radiographic findings. An attempt was made to confirm the diagnosis by culturing material obtained from the involved disc space in all but three patients. A radiologic investigation (plain x-ray, bone scan, CT scan, MR imaging) was considered consistent with disc space infection if so designated by the radiologist interpreting the study.

Results

Of the 35 patients with disc space infection, 21 (60%) were male and 14 (40%) were female. The patients' ages ranged from 9 to 75 years with an average of 53 years. Table I lists the predisposing factors for the development of discitis. Nineteen (54%) of the patients underwent prior intervertebral disc surgery and 7 (20%) had another infection which hematogenously may have involved the disc space. Other predisposing conditions included diabetes mellitus, cancer, renal failure, previous discography and intravenous drug abuse. No apparent predisposing factor was discovered for 3 patients.

Table I.
Predisposing factors

	No. (%) patients
Intervertebral disc surgery	19 (54)
Other infection	7 (20)
Diabetes mellitus	6 (17)
Cancer	2 (6)
Renal failure	2 (6)
Discography	1 (3)
Intravenous drug abuse	1 (3)
None	3 (9)

As shown in Table II, the majority [27 (78%)] of disc space infections were located in the lumbosacral spine and less commonly in the cervical and thoracic spine. Table III highlights the organisms responsible for discitis. Staphylococci (both *S. epidermidis* and *S. aureus*) accounted for 20 (56%) of the isolates followed less frequently by viridans streptococcus, *Escherichia coli, Proteus mirablis, Pseudomonas aeruginosa* and *Bacillus sp.* Seven patients had either a negative culture or no specimen was obtained. Additional laboratory data consisted of a mildly elevated white cell count (average 11,280, range 5,170 to 27,290 cells/mm^3) and an increased erythrocyte sedi-

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Table II.
Location

	No. (%) patients
Lumbosacral spine	27 (78)
Cervical spine	4 (11)
Thoracic spine	4 (11)

mentation rate (average 57, range 19 to 120 mm/hr).

The clinical findings of disc space infection are described in Table IV. The two most common symptoms were localized spinal pain in 34 (97%) patients and fever in 15 (43%). Less often leg paresis, altered mental status, weight loss and urinary incontinence were encountered. The time from the onset of symptoms to diagnosis extended from 2 days to 9 months and averaged 7 weeks. Table V displays the radiologic investigations of discitis. Plain x-ray, CT scan, bone scan and MR imaging revealed results consistent with disc space infection in 68, 83, 93 and 100% of studies performed, respectively.

All patients received antimicrobial therapy which usually was administered intravenously for a prolonged period of time (4 to 6 weeks). Initially patients were placed at bedrest and fitted with a thoracolumbar orthosis, neck collar or halo vest when ambulatory. Surgical drainage was required in 17 patients and in addition 1 patient each underwent strut graft placement and Harrington rod insertion. All patients survived and there were no recurrences of discitis but follow-up was limited in many cases. Three cases suffered neurologic deficit in the form of leg paresis and urinary incontinence.

Table III.
Microbiologic results

	No. (%) patients
Staphylococcus epidermidis	10 (28)
Staphylococcus aureus	10 (28)
Viridans streptococcus	3 (9)
Escherichia coli	2 (6)
Proteus mirablis	1 (3)
Pseudomonas aeruginosa	1 (3)
Bacillus sp.	1 (3)
Negative culture of no specimen obtained	7 (20)

Table IV.
Clinical findings

	No. (%) patients
Localized spinal pain	34 (97)
Fever	15 (43)
Leg paresis	2 (6)
Altered mental status	1 (3)
Weight loss	1 (3)
Urinary incontinence	1 (3)

Table V.
Radiologic investigations

	No. performed	*No. (%) consistent with discitis*
Plain x-ray	31	21 (68)
CT scan	23	19 (83)
Bone scan	15	14 (93)
MR imaging	7	7 (100)

Discussion

Disc space infection is considered an uncommon disease[8] with various centers reporting one to three cases per year.[1-7] In contrast we report 35 cases over a seven year period for an average of five cases per year. A variable sexual preference has been noted in patients with discitis[4,7] and in our experience males outnumbered females. In articles describing disc space infection in adults, the average age of patients extended from 40 to 55 years[4-6] and in our series it was 53 years even though we included children.

There are two main pathogenic mechanisms which predispose to discitis. Direct inoculation, commonly following surgery on the intervertebral disc, is frequent in adults and also has been described following lumbar puncture, myelography, paravertebral injection, discography, lumbar sympathectomy and epidural anesthesia.[5] Prior intervertebral disc surgery was the leading predisposing event in our patients and one case followed discography.

The other principle pathogenic factor, hematogenous dissemination to the disc space from a distant focus of infection, is predominant in children because of the infrequency of spinal surgery in children and the loss of vascular supply to the intervertebral disc with aging.[1] Although only two of our patients were children, hematogenous dissemination accounted for seven cases of disc space infection and presumably a similar mechanism was involved in the patient who was an intravenous drug abuser.

The lumbosacral spine is the most frequent location of discitis in our experience as well as in the experience of others.[1-6] This reflects, in part, the higher frequency of disc surgery performed on the lumbosacral spine in adults but its explanation in children is unknown.

Although some authorities have proposed a non-infectious etiology for discitis in children,[1] most studies support an infectious cause with staphylococci the most frequent isolates.[2-7] Other laboratory data have included a normal to mildly elevated white blood cell count and a high erythrocyte sedimentation rate.[1,5,8] In our series staphylococci were recovered most often followed by streptococci and gram-negative organisms

and both the white blood cell count and erythrocyte sedimentation rate were increased.

The clinical picture of disc space infection is dominated by severe spinal pain localized to the site of infection with possible radiation to the extremities, flank, abdomen or perineum. Because movement exacerbates the pain, patients often remain immobile. There is usually a pain-free interval extending from days to months in patients with discitis following intervertebral disc surgery. The pain resulting from disc space infection may mimic that of pyelonephritis, renal calculus or acute abdomen. Associated with the pain are paravertebral muscle spasm, fever and chills.[3,5,8] In our patients localized spinal pain almost uniformly was present but fever appeared in less than one-half.

Disc space infection has been characterized as "elusive"[8] which probably accounts for the prolonged interval from onset of symptoms until diagnosis and in our experience averaged seven weeks. Radiologic findings suggestive of discitis may be delayed or nonspecific and when possible should be confirmed by culturing blood or material obtained from the involved disc space. Plain x-ray of the spine initially reveals disc space narrowing and erosive irregularities of the adjacent vertebral margins progressing to disc space obliteration and bony fusion. Bone scan typically discloses uptake in the infected intervertebral area but cannot be differentiated from normal postoperative changes. CT scan has been reported to be very sensitive for the diagnosis of disc space infection and also shows the extent of the inflammatory process. The experience with MR imaging is limited but appears favorable.[1,4-6] In our series bone scan and MR imaging most frequently provided results consistent with discitis while CT scan was only slightly less accurate.

The treatment of disc space infection consists of three modalities: antimicrobial therapy, spinal immobilization and surgical intervention.[4,6,8] Reports of discitis in childhood vary in recommendations for administration of antibiotics with some favoring their use[2] and others advocating none unless symptoms persist.[1,3] Although earlier articles describing disc space infection in adults disclosed excellent results without antimicrobial therapy,[9,10] such treatment has been rendered in more recent series.[4-6] Usually an antistaphylococcal agent is administered intravenously for at least six weeks with modifications made on the basis of culture results.[4,6] Prolonged oral therapy also has been successful.[5] The vast majority of our patients received prolonged intravenous antibiotics.

Some form of spinal immobilization is encouraged by most authorities. Various recommendations include strict immobilization in a spica cast,[9] modified immobilization with bedrest[6] and early mobilization in a thoracolumbar orthosis or halo vest.[8] In our series immobilization was achieved by bedrest followed by placement of a thoracolumbar orthosis, neck collar or halo vest when patients were ambulatory.

Operative procedures are indicated in the following situations: negative blood or closed biopsy cultures, failure of medical therapy, neurologic deficit, paravertebral abscess and progressive spinal deformity. At surgery the disc space is debrided and fusion is performed for cases unresponsive to conservative therapy.[8] Almost one-half of our patients required operative evacuation of the disc space coupled with strut graft placement and Harrington rod insertion in two patients.

Discitis is associated with a uniformly good prognosis in both children[3] and adults.[5] Mortality approaches zero and recurrences are uncommon but morbidity in the form of residual back pain, limited spinal mobility and neurologic deficit are more frequent.[7,8] In our series all patients survived and there was no relapse of infection but neurologic deficit consisting of leg paresis and urinary incontinence occurred in three cases.

Acknowledgement

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For 'Quality' Read 'Cost'

Editor, Alabama Medicine

In the February 3 issue of *The Alabama MD*, there was an article entitled "An Open Letter From Medicaid DUR." The Drug Utilization Review Program of Medicaid, as physicians are now aware, is a new level of bureaucratic control on the prescribing habits of physicians.

Although it is true that the purpose of the Alabama DUR Program is ostensibly "to improve patient care by reduction of drug side-effects and untoward reactions; serve as an education tool; and aid in the proper selection and utilization of medications thereby reducing costs," one would be foolish to believe that cost control and control of physician prescribing habits is not the ultimate true aim.

In addition to advising physicians of the proper utilization of drugs such as H2 antagonists, much of the open letter addressed the high cost of H2 blocker therapy.

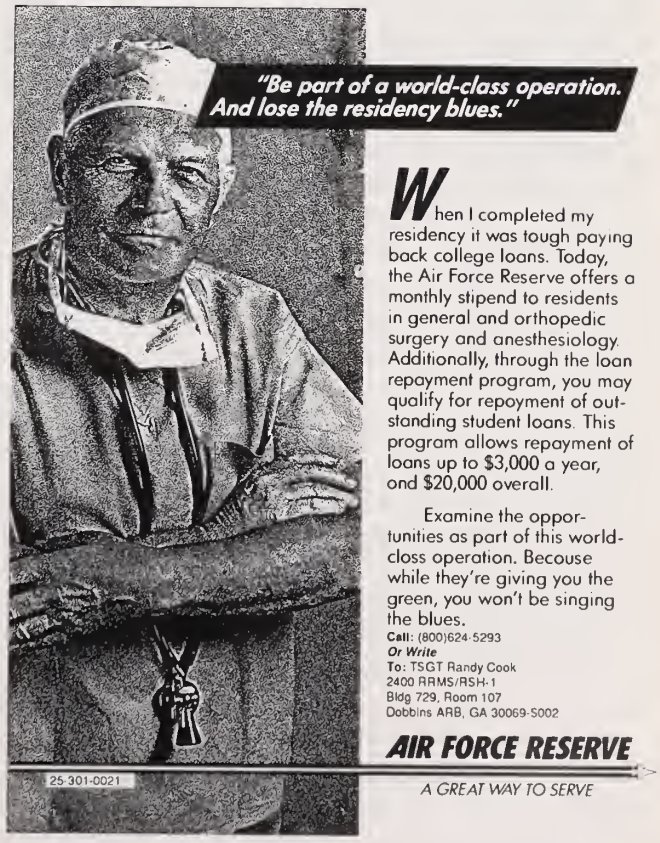
While helping to "educate physicians," a huge amount of data is being accumulated surreptitiously in the computer data banks about the prescribing habits of physicians. Although there is anonymity currently in the evaluations that are being done, the data is within the computer to analyze physicians specifically. Who knows what this data will be used for in the future.

At the end of the open letter, the reader is then referred to an article submitted by the DUR to *Alabama Medicine* which was entitled "The Appropriate Use of H2 Receptor Antagonists" by Howden. This article outlined the on-label recommendations for H2 blockers and summarizes this. Dr. Howden then adds his opinion that these are appropriate uses of the drugs. While I do not want to get into here the argument of whether or not off-label uses of drugs are appropriate, I would like to comment on the principle of having what is perceived as a medical journal being misappropriated as a means of disseminating the State position on utilization of drugs. What makes this onerous is its submission by a government regulatory agency and its linkage with the agency's goal of "educating physicians" to treat patients more appropriately, i.e. by their standards.

When viewed in conjunction with the open letter and the educational letter sent out to physicians requesting a reply regarding the perceived improper prescribing habits that many physicians now have, this becomes a disturbing practice. In the article, Dr. Howden appropriately states that certain things are his own opinion, however, when this reading is recommended by a State agency for all physicians, it takes on more weight than just his opinion. It becomes a set of quasi-official guidelines.

While it is difficult to determine exactly where the dissemination of information ends and the heavy hand of government guidelines begins, I would suggest that in this case that line may have been crossed. I would urge the State Medical Association, through its official publications and journal, to make every effort to clearly distinguish articles that are submitted by authors as research or review from those that are being planted by the State to further its regulatory and bureaucratic agenda.

Edward R. Teitel, M.D.
Ozark, AL 36360



"Reflections From a Dean"

Albert W. Pruitt, M.D.

Each day, most of us encounter discussions of major changes that may occur or are occurring in health care in this country. Certainly this is a frequent topic in our daily newspapers and all of our professional news publications carry stories about health care reform in nearly every issue. In our daily activities, almost anytime groups of physicians or health care administrators gather, the likelihood of dramatic change in some aspect of health care or health care delivery is discussed, and often with considerable emotion. Interestingly such discussions do not deny the need for change — we all have a list of weaknesses we have noted in our system of health care delivery — but such discussions do usually include an overlay of anxiety or apprehension about what might be in store for the medical profession. The extent of that apprehension is an interesting topic, as well as are the reasons for it, and likely include the sense of threat or vulnerability that the probability of change engenders. As we anticipate change, we must be concerned with three things: the impact on our patients, on our students and on our research. It is on these three that I would like to focus.

Let us begin with some reflections about the first, that is, our patients. In the best of all worlds, we would like to think that major alterations in health care delivery are being proposed primarily to provide patients with even better care than that which is now provided. As we all know, however, simple patient need is not the only item on the agenda. Appropriately, reform plans now under consideration at national and state levels, are all stressing improved access, quality of care and cost control. The goal of universal access for patients is one that I enthusiastically endorse, but we know that providing entitlement to someone for a service is not the same as having the person receive the service. It is thought that at any one time in this country, about 37 million people are uninsured by any company or program. Depending on geography, the profile of a non-covered group will vary considerably. However, the simple arrangement of reimbursement for services provided will not necessarily mean better care for all of the 37 million. We know that because we have extensive experience with individuals who do not appropriately use medical services, although they now have some form of reimbursement coverage. I still vividly remember standing with a senior physician outside the Brigham and Women's Hospital in Boston as he described the sophisticated services provided to thousands of obstetrical patients in that facility. He then looked up the hill within two miles of the hospital and expressed dismay that in spite of all the care available in the hospital, pregnant teenagers who lived in that part of town still did not come for care until they went into labor, all to often prematurely.

Physicians who practice in rural areas have similar stories and recognize other obstructions that keep patients, who do have financial coverage, from reaching the physician they need. We don't know all of these impediments: they include lack of education, lack of motivation, pre-occupation with more urgent matters such as personal safety, previous intimidation by the health care system, (we each can construct a list); but we know that for many of our neediest patients, an arrangement for reimbursement will not mean universal access. Anytime I am lulled into thinking that, I remember the images of the towering hospital and the nearby hill with people who, for whatever reasons, do not come to that tower.

Reflecting on the hospital tower, especially that hospital tower, leads me to think about all of the mergers of hospitals and various health care companies that are taking place all across the country. The Brigham and Women's is merging with the Massachusetts General, Barnes Hospital is merging or becoming otherwise intimately associated with several other hospitals in St. Louis and the list continues to grow with startling announcements of previously fierce competitors now joining together. The drama of all this reminds me, in some ways, of the short-lived era in the 1980s of hospital diversification — when many hospitals established or purchased companies that had only slight or no relationship to health care services. One must wonder what the impact will be on patients as hospitals, who were formerly competing, begin to merge into one institution. This is happening not only between the most prestigious not-for-profit hospitals, but also in the for-profit sector as one company, with a chain of hospitals, joins with another and then another. Such mergers are completed, it is said, to enable the hospitals to negotiate more effectively in the future and maintain

their patient populations. Somehow the individual patient looks especially small in the face of big business. Will these new institutions, in some way, be able to open their doors more widely than in the past and reach those who have been reluctant to come?

Another proposed development is the enrollment of as many patients as possible in a Health Maintenance Organization or other managed care arrangement. Such a proposal focuses especially on controlling the cost of medical care. In addition, many managed care organizations have a good record of monitoring the quality of care received by the patients — thus addressing another goal of health care reform. In making these changes toward incorporating patients into groups that may be, it seems, distributed to physicians by the managed care company, it is important that we, as physicians, do not lose the personal relationship with the patient. There is the temptation, I believe, to deal with the patient's agent and to begin to think of the accountable health plan as the primary focus — in commercial terms, as the customer; and thus gradually see the valuable, cherished personal interaction between physician and patient quietly fade away.

Do not misunderstand, neither the merger of big institutions into even bigger institutions nor the dramatic expansion of enrollment in Health Maintenance Organizations is inherently bad or the wrong thing to do. On the contrary, the wisest minds in this country believe that these approaches are the best paths to follow. We are however, still in an era that picked up considerable steam in the 1980s — an era of dramatic commercialization in medicine; an era that encourages growth of companies, promotion of services, competition between providers for market share and the designation of patient as customer. In such an environment, my contention is that we need to maintain the sensitivity to the individual patient that has so characterized the practice of medicine in this country for decades.

Turn now to some reflection on our students, for this is another group that needs our advocacy as changes are proposed and made in health care delivery and education. As has always been true, our students are subjected to considerable stress. They come into medical school having prevailed in the pre-med arena in which there are often as many foes as friends and having withstood the competition throughout the admissions process. The extent of that competition we all know: applications nationwide are at an all-time high — 42,762 for the 16,307 places; at the University of South Alabama College of Medicine, about 500 Alabama residents apply for the 64 positions and there are hundreds more out-of-state applicants; students on-average apply to 10-12 schools to improve their chances of success; and those who are not successful know that career opportunities in many other fields are seriously limited.

Once in school, the curriculum is tough but all medical students expect that. Another major stress, however, is the accumulation of debt as the students deal with tuition, other school expenses and the cost of living. As a result, 80% of graduating medical students nationwide are in debt with the average debt being near $60,000 and climbing each year.

Such debt is thought to influence specialty choice. Furthermore, a level of freedom and flexibility in deciding specialty choice through residency selection is a matter of serious concern for students.

In my discussions with medical students, they recognize the need for increasing numbers of primary care physicians and vigorously support that effort. They also understand the career opportunities that are developing in family practice, general internal medicine and general pediatrics. These market forces are clearly acknowledged, and students talk of responding to such forces because of the opportunity, but especially because they want to respond to patients' needs for comprehensive care. The other half of the debate in the promotion of generalism, however, is regulation. Medical students, like most physicians, respond very negatively to change in regulation of residency training positions. Reduction in number of particular specialty slots for training is threatening to students even though the interest in primary care residency seems to be growing. As physicians who are well along in our careers, if we truly endorse the education of many more generalists than were educated in the past, it will be helpful if we stop giving students mixed, negative and conflicting messages about careers in general internal medicine, family practice and pediatrics.

Another way in which we should maintain a high level of sensitivity to students' needs is in guaranteeing an environment that allows extensive, appropriate interaction between medical students and patients. As we move into a period with even more emphasis on efficiency and cost effectiveness, it may become difficult to provide students with the extensive clinical experiences they have enjoyed in the past, and there may be pressures to move the students to the sidelines as observers of medical practice. One of the very important features of our system of medical education has been the variety of clinical experience that U.S. medical students have and the extent of their involvement in patient care. This breadth of clinical exposure is certainly not common in all countries.

I'm sure each of you can recall the role you played in patient care, as a medical student, and how positively

you responded to being a part of the patient care team.

I recall, as a young faculty member, being on rounds one day with a cardiology entourage. As was often the case, probably twenty people of all levels of training and professorship gathered around the chief of medicine, who also happened to be a renowned cardiologist, as he led the group from bed-to-bed to evaluate patients, teach and discuss disposition.

After hearing Mr. Johnson's case presented and thoroughly examining the patient's heart and neck veins in a way that probably even today would preclude the need for an echo, the chief explained to Mr. Johnson the extent of the problem and his recommendations for management, which (as I recall) probably included valve replacement.

Mr. Johnson was most appreciative, and with all humility and reverence for the stature of the chief, thanked the chief and told him that before agreeing to such surgery he would have to get his student doctor's advice. Needless to say, the junior medical student doctor was aghast, but that kind of involvement of students in the care of patients, we should not lose. With this story, I do not mean to romanticize the inpatient setting, the ward team and the attending rounds, but to stress the need for involvement. Certainly our students, at times, have not received the teaching in ambulatory settings that they need, and we have been excessive with some of their tertiary care experiences.

Nevertheless, upon graduation, American medical students know how to evaluate patients and how to interact appropriately with patients. The fact is, the young student needs to spend time with patients whether in the hospital or in the office, and a system that excessively stresses the through-put of patients per hour in the name of efficiency and cost effectiveness will likely not permit the connection we need to take place between student and patient.

Finally, let us reflect briefly on the position of research in the context of a health care reform environment. My first thought about this is that research, especially biomedical research, is receiving very little attention in the face of major health care delivery issues.

Biomedical research in this country is, by far, the best in the world. Scientific discoveries, technology development and carefully conducted clinical investigations, are at the core of our medical practice. The conduct of this work is not easy, often is expensive in terms of time and money, and requires the energy of inquisitive and creative scientists and physicians; but it is absolutely essential if medical care is to continue to advance.

The cost of carrying out this research is spread across several sectors and includes federal government, industry, foundations, contributions from individuals, hospitals, academic institutions and others. Landmark discoveries and developments have come from research supported by all of these mechanisms. The concept of receptors, the development of beta blocking drugs, the description of metabolic pathways, the production of vaccines — the list goes on and on — have all come from well conducted research, and these investigations have enabled us to practice medicine the way we do today.

An interesting, recent survey by Research America shows that the American people have a substantial appreciation for medical research. In that survey, the population expressed an encouraging willingness to support research through tax dollars.

As practitioners of medicine and especially as physicians who appreciate the direct importance of research to patient care, we need to promote the key role that research has in medical practice and to make certain that support of research is seen as integral to comprehensive health care in this country.

In conclusion, although I spoke as I began of the apprehension that seems to overlay the discussions about change in health care, let me say that I look forward to the future with positive anticipation. I believe that when we work from a position of advocacy for our patients, our students and our research, we will continue hopeful about the future of American medicine. We will continue to take price in what we do and how we do it.

As Jerry Mashaw has said in a recent issue of *Domestic Affairs*, "...I must confess that I believe we can take the bashing of the health care system too far. An industry that grows at twice the rate of the gross domestic product, creates a huge number of high-paying, high-skilled jobs, provides the United States with technological leadership in a major economic sector, and is virtually immune from foreign competition should hardly be treated as public enemy number one."[1]

To this I would only add: hear, hear!

[1]Marshaw, J.L. Taking federalism seriously: the case for state-led health care reform. *Domestic Affairs* 1993; 2:1-21.



Mrs.William Hall
A-MASA, President

A-MASA Facing Medical Issues Today

It has been my honor and pleasure to serve on the AMASA Board for the 1993-1994 year and to work for this unique organization. If ever our spouses needed our support, it is now. If ever our communities needed our health advocacy, it is now. If ever the medical family needed our encouragement, it is now. If ever the need was there for a strong, vital and growing auxiliary, it is now!

We live in a time when the physicians of this nation are providing the best medical care in the world ... yet, much of the public thinks physicians are self-serving, that physicians are committed to the quantity of compensation, rather than to the patient care. We live in a time when technology fosters progress never dreamed of ... yet, scientific knowledge is pitted against ethical questions never thought of, let alone asked. We live in a time when organ transplants offer new life to the dying ... yet a suit-happy society no longer accepts that some babies are born deformed, some diseases cannot be cured or that the natural process of aging will inevitably end our lives. We live in a time when people are living longer, healthier lives than ever ... yet, the government imposes increasing restrictions that let cost dictate the limits of care. We live at a time when we have conquered most of the killing childhood diseases ... yet, we are faced with the dread specter of AIDS, with no vaccine or cure in sight. We live in one of the wealthiest, most developed, democratic countries of the "civilized" world ... yet, violence has invaded the very heart of society - the home.

The pressure these issues bring give us no cause to wonder why medical families face so much stress ... why many physicians are leaving the profession to which they had committed their lives.

Our state auxiliary is working with MASA to confront these difficult issues and to make a difference in our communities. They have coordinated with A-MASA an Executive Staff Assistant, a grass roots physician image program with their public relations department, an address change to the home for the *Alabama M.D.* and AMPAC provided the speaker, Melinda Ferris from Washington, D.C. who gave an outstanding program at our Winter Leadership Conference on Campaign Management.

As medical policy and decisions are increasingly made by legislative bodies ... we must continue to educate physicians' spouses about the issues so they will be knowledgeable and ready to become involved in the crucial legislative process. This year we have an added opportunity to make our voices heard. This is an election year ... a time when the citizens of this state will choose their future leaders.

While the focus of the Auxiliary is legislative rather than political activity ... we must use this opportunity to make our presence felt by knowing the issues and the candidates and by casting our votes for those who will listen to the concerns of physicians and their patients ... those who will take a reasoned approach in making the laws and regulations that increasingly govern medical care. Health care is a powerful issue of the 1994 elections and caregivers need to have their say in their destiny. Anne Marie Gormley, our legislative chairman, has worked extremely hard this year to keep us informed on the issues.

Beyond legislative action there is another way we can help to maintain excellence in medical care. That

is by renewing our commitment to medical education. As government and other sources of funding for medical students and medical schools are drying up, support of the American Medical Association Education and Research Foundation becomes even more critical if medicine is to continue to attract the brightest minds. The tradition of excellence for which we have worked so hard should continue to be the norm. Across the nation, auxiliaries helped raise almost three million dollars for AMA-ERF. Joy Murphy, AMA-ERF Chairman is proud to present a portion of these funds to Alabama Medical Schools.

Our commitment to make a difference is also needed to promote good health in our local communities. Except for the direct physician/patient relationship, we as auxilians can have the **most** positive influence possible on the image of our physician spouse. Every time we fundraise for the less fortunate in our community, work in our adopted school, work to sponsor a health fair with patient screening for certain diseases, or educate the public about medical problems and other health projects, we can have a positive influence on the image of our physician spouse. Every time we establish contact with our legislators, work on campaigns and raise funds for them we can have a positive influence on the image of our physician spouse. Every time we write a check at the grocery store and the clerk identifies us with our physician spouse we are helping to form the public's perception of the medical community.

Usha Bhuta, Membership Chairman and Emily O'Toole, Health Project Chairman have worked with our membership this year to provide materials and support for the counties. Twelve presidents elect attended leadership conferences in Chicago and the fall and winter board meetings were devoted to leadership training and understanding the issues facing medicine today.

The issues are tough and real. Our ability to make a difference depends on our commitment to another cause, and that is keeping the organization vital and growing. We are brought together in a federated structure of county, state and national levels. We have within the auxiliary an infinite variety of inate talents, gifts and abilities. We have the intelligence, movitation, initiative and creativity to meet any challenge. We, also, as physician spouses have unique privileges and opportunities. We have access to information and resources. We have entre' to other organizations, institutions, and agencies. We have strength from our ties to organized medicine.

The Medical Auxiliary that began as a social organization for spouses has become an invaluable and irreplaceable part of the medical profession. We are the public relations component of the profession of medicine.

If you wonder what is happening that is positive for the medical community or where is the silver lining...look no further. It is your auxiliary. It is you!

Let us work to be sure that the perception this country has of the medical community is one of unity, strength and devotion to our community health care.

Donna Gosney, your president for 1994-1995 is most capable and we look forward to assisting her in a very challenging year to come.

Linda Hall, President

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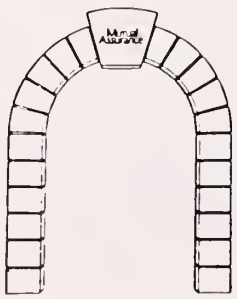
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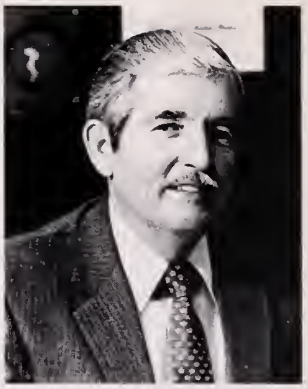
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EXECUTIVE DIRECTOR



S. Lon Conner
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The Search for Simplicity

Some years ago, Dr. Edward Teller, the physicist, published a small book entitled *The Search for Simplicity*. He wrote of man's efforts over the centuries to find order amid the seeming chaos of the physical world, paying due credit to Plato and Aristotle, Galileo, Newton, et al — thinkers who had labored to find, not always successfully, the fundamental laws of nature.

The title stuck with me long after the contents had faded into the fog of memory. After all, The Search for Simplicity pretty well captures most of the lofty aspirations of the human spirit. That search has led mankind down a long road, littered here and there with the shards of shattered beliefs and abandoned theories. The search will never end. Just as there have been many in the past who have embraced false idols or junk science, so will there be many in the future who will go to their graves terminally disappointed they had not found the whole answer in their science or their philosophy. In the end, the wonder and beauty of life owe much to the eternal mystery.

Even the mind of Einstein never found perfect peace in his search for simplicity. He died looking for a unified field theory — a concept, I take it, that would finally explain everything. All of us look for something like that along the trajectory of our lives, although on a somewhat lower plane than his.

We can even look at the current debate over health care reform, often chaotic, and realize that the most seemingly confused theories may be, in the final analysis, sincere searches for simplicity, for irreducible absolutes. Or, at the very least, their authors profess to think so.

Einstein believed his absolute was out there somewhere, and confessed to being appalled by the new theories of quantum mechanics, particularly the "Uncertainty Principle" of Werner Heisenberg, which held (according to the book I just consulted) that:

"...the product of the uncertainties of our knowledge of the values of conjugate variables (such as position and momentum, or energy and time) is always greater than Planck's constant. Thus the more accurately we know the position of an electron, the less we know about its momentum."

Hence, the Uncertainty Principle, which paved the way for the hypothesis of the "quantum leap," whereby an electron could leapfrog over one orbit to a third *without having ever having occupied the intervening space.*

To say all this is Greek to me would insult the Greeks. I have no earthly idea of the underlying math or anything else about particle physics. The quantum leap sounds absurd to me. But I take some simple pleasure in the fact that Einstein said that if he were convinced that that the uncertainty principle was valid, he would rather have spent his life as a clerk than as a theoretical physicist. "God does not shoot dice with the universe," he is supposed to have said in consternation. But he seemed to fear that Heisenberg was on to something immensely disturbing to his own search for simplicity.

In a very real way, this high-domed debate is a metaphor for the health care debate. People like Ira Magaziner, the designer of the Clinton Health reform plan, are convinced they have identified and quantified all the variables, making neat absolutes of them all, and that only the very ignorant would question them. Stripped of the complex verbage, Mr.

Magaziner would quantum-leap the health care system from point A to point Z, blithely ignoring the intervening obstacles. Somebody should tell him he is not an electron.

Such regimentation as he proposes would force the country into a lock-step mode that is 180-degrees out of phase with the American way of life. I happen to number myself in the camp of those who believe this. But I might concede that Mr. Magaziner and the Clintons are utterly sincere in their conviction that they have seen the one true light, even as others, with plans as different as day from night, are just as persuaded that their way is best. (Some, of course, have merely offered plans as a place to sit while they watch to see which way the wind blows, if it blows at all.)

But I am tempted to believe that all the partisans, the President included, have come to realize in the past year or so how incredibly complicated this problem is. To admit that, of course, would be to admit their inadequacy, an admission totally alien to the political persona.. Although we may get some vague idea of the scope when we say we would be remodeling one-seventh of the U.S. economy, a fraction that should boggle the mind, we are still talking abstract numbers, not human beings with dreams, fears, pain, needs and aspirations that cannot be relegated to a computer program without gross distortion.

Just as no one can say with any assurance how much the Clinton Plan — or the Cooper Plan, or the Chafee Plan — would cost in dollars, no one could even presume to invent a formula that would incorporate the human cost.

There is a considerable difference between an institution that has evolved over time, correcting itself all along the way, as the vaunted American health care system has, and one prefabricated in a vacuum and imposed from without. I believe the President has been less than forthright in his promises on the stump that his plan would assure universal, permanent coverage to everybody — coverage that can never be taken away and for which the total bill would be little more and probably less than the nation is now spending.

I grant the President's sincerity about wanting reform, but if he, certainly a man of above average intelligence, sincerely believes in the numbers he has been citing, that phenomenon can only be explained by the venerable observation of a wise man, before Christ or Caesar: "We believe what we want to believe."

For the sake of the current discussion, let us assume that his system is enacted and imposed and, ten years down the road, his predictions are confirmed. That would only come to pass, I firmly believe, if a federally mandated Bed of Procrustes is forced on the population — calculated, draconian rationing, sacrificing human capital on the altar of double-entry bookkeeping.

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One of the corollaries of the Uncertainty Principle is that in sensitive systems the very act of observing alters the nature of what is observed. In the past couple of years the public has been subjected to so many endless polls, even as it was being systematically propagandized by hundreds of conflicting interests, that it may not be the same public now as it was when Mr. Clinton took office.

Sea changes have been noted by tracking polls, but I am thinking of something more fundamental, a reversion in which the popular mood may have shifted all the way back to its condition before the cacophonous debate began; before the Pennsylvania senatorial election in late 1991 persuaded the pundits that the American people were demanding a top-to-bottom revolution in health care.

An awful lot of time and money has been spent on that assumption, which may no longer be valid, if it ever was.

Perhaps it never was much more than people searching for simplicity but who found, instead, complexity and duplicity — and are giving up the quest, perhaps slowly realizing that while some reforms are needed, dismantling the present system to accomplish that would be a national disaster of unimaginable impact.



James E. West, M.D.
President, MASA

President's Report*

I have spent much of my presidential year speaking around the state on health care reform. Similarly, the Board of Censors has spent many hours listening to experts on managed care and discussing the various options and pitfalls presented by the fluid situation in Washington.

Additionally, nine members of the Board are serving on the Governor's task force to monitor federal action on health care reform and to make recommendations for whatever state action is indicated.

Early in this nation's Intercontinental Ballistic Missile program, high priority was given to countermeasures, the anti-missile missile. One rocket expert framed the problem in these words: "Have you ever thought how difficult it would be to hit a bullet with a bullet? That's our mission."

It pretty well describes the problem of your officers and board members in the past 12 months. The targets appear and disappear with baffling speed and frequency.

When I assumed the stewardship of this office in April 1993, the expectation – or, more accurately, the anxiety – was high that health care reform was a speeding locomotive that would demolish everything in its path.This feeling had been building since the closing months of 1991, when a relatively obscure academic, Harris Wofford, upset Dick Thornburg, the odds-on favorite in the Pennsylvania Senate race.

While political upsets do not normally galvanize physicians into action, this one did for the reason that Mr. Wofford made the perceived need for health care reform the major issue, charging the Bush Administration with total neglect, and thus tarring Mr. Thornburg, who had been U.S. Attorney General, with that same brush. Mr. Thornburg had boasted in his campaign of his familiarity with the corridors of power in Washington by virtue of his having served the administration. What would normally have been an asset proved a fatal liability. Wofford successfully charged him with being part of the Bush Administration's indifference to "the health care crisis," as he termed it.

Even political experts were shocked by the sudden emergence of this as a controlling issue, one thought to have been well down the list of voter concerns – important, yes, but not paramount. Pennsylvania was the first hard evidence that health care reform was indeed a hot-button public issue.

In the presidential race the following year, Mr. Clinton exploited it for all it was worth. That strategy was hardly surprising; his chief strategist had also been Mr. Wofford's in Pennsylvania. Which is not to say it was a totally new issue. After all, virtually every President since FDR had entertained some idea of national health insurance. The AMA had seized the initiative long before Pennsylvania with its Health Access America program.

Looking back, it is plain that the Clinton forces made at least two major mistakes that ultimately weakened their case, as we are seeing now in 1994.

During the presidential campaigns of 1992, Mr. Clinton had promised a reform bill within 100 days of taking office. Instead it was fall before he announced his plans and close to year's end before the massive 1,400 page bill was actually presented. During the long, hot summer and autumn public enthusiasm had begun to yield to second thoughts.

It began to dawn on Americans that the task would be monumental and would probably call for a gargantuan new bureaucracy to run it. Dug up from the past was a statement once attributed to a famous news commentator: "World War II was the last federal program that worked."

With that realization came another: the cost would be huge and Mr. Clinton was not shooting straight in his rosy projections of a program that would pretty much pay for itself through the elimination of fraud, waste and abuse, and by radically reducing insurance company profits. But what had been effective on the

As presented at annual session, Orange Beach, April 1994.

stump became an albatross in the Oval Office. Clinton had to produce the miracle he had promised. Inevitably, his plan had to rely on smoke & mirror funding, a form of transparent magic that seems to amuse taxpayers less and less with each passing session of Congress.

Thus the first major mistake was that Candidate Clinton had promised far more than he could deliver. The message he had given in the campaign was, at bottom, the promise of virtually free health care for everybody. A chicken in every pot, pie in the sky. It is unfortunate that this still works well enough with portions of the electorate to seduce politicians into perjuring themselves. Yet, to paraphrase Mr. Lincoln, modern-day Americans don't stay fooled long.

The second major mistake was the turning over of the whole bill-writing process to a secret cabal of technocrats, from whose ranks those closest to the health care problem were excluded, including the AMA, which had had the problem under intense study when Mr. and Mrs. Clinton were still preoccupied with feathering their nest back in Little Rock. Perhaps remembering the government-within-a-government assembled during Iran-Contra days by Colonel North, Admiral Poindester, the late Bill Casey and others, Americans were highly suspicious of these secret doings.

Already, distrust of everything about Washington had reached historic peaks. Millions of Americans didn't cotton to an issue as intimate as their health care -- and indeed their very lives -- being stamped Top Secret by the new Washington crowd.

The Katzenjammer Kids who had waged Mr. Clinton's successful campaign were so infused with the sense of their own power and invincibility that, when they swarmed into the White House, they figured they could get by with breaking all the rules. They failed to understand that they had not beaten George Bush; that, assisted by an ailing economy, Mr. Bush had beaten himself.

When the first bumper stickers began asking "Who Elected Hillary?" the White House staff failed to comprehend they were no longer outsiders who had rushed in to save the people from the Washington crowd but were suddenly insiders themselves, and thus objects of public suspicion, distrust and even scorn.

In the fall, however, Mrs. Clinton achieved a brief and deserved fame in her competent and articulate appearances before congressional committees, one of which departed from custom and gave her a standing ovation. She is undeniably a woman of intelligence, competence, and persuasive power.

The young White House staff was delirious: she had turned the tide and passage of the impending bill, with minor alterations, would be sustained by a massive outpouring of public support. It seemed for a few weeks that the White House Christmas would be a merry one.

Then the appallingly complex Ira Magaziner reform bill, all 1,400 pages of it, was published. In retrospect, the bill's morbid obesity may have had more to do with the undoing we have seen than even the doubts cast by Harry and Louise, the couple in the highly effective TV commercials sponsored by the Health Insurance Association of America.

But the Whitewater revelations also played a big role. While no solid proof of criminality has yet been shown, the details have certainly demonstrated the Clintons' venality. This has been particularly devastating to Mrs. Clinton's calculated image as a kind of non-political savior of a suffering society, driven by the purest of altruistic motives, somewhere between Joan of Arc and Mother Teresa.

Suddenly she appeared to be just another opportunistic politician, as avaricious as the next one. Thus the Clinton Health Care reform crusade was hit at the turn of the year by a disastrous series of blows –

- The very size and complexity of the proposed legislation itself, with its plan for a radical government take-over of medical care;
- Whitewater and the inevitable credibility burden;
- the crescendo of doubts cast by critics, political and private, convincing great blocs of Americans that instead of the pie-in-the-sky they had been shown in the '92 campaign, it now appeared that they stood to pay more for less.

Add to these doubts those being cast by the unprecedented military array of 700 or 800 health care lobbies pouring out tons of alarming material from more points of view than any intelligent voter could hope to absorb, and you have the recipe for gridlock, deadlock and stalemate, all rolled into one confused ball of wax.

A year hence, my successor may have the answers, but for now all that can be said of what may transpire in Congress can be summarized by Sir Winston Churchill's description of Russia – "a riddle wrapped in a mystery inside an enigma."

§§§§

And now I must take my leave of you. While I have not fully satisfied my objectives for the year, I have given it my best shot in a bewildering time of change. A fair grade for my efforts might be the famous epitaph on the old farmer's grave in a country churchyard cemetery: "He Done his Damndest."

I shall always treasure the high honor and privilege of serving as your President. Let me end my tenure as I began it by urging all of you to work with your Association in all its many endeavors – uppermost in this critical year being health care reform. **You can make a difference!**
Thank you.

Equipping The Pool For Maximal Rehabilitation Benefits

Richard T. Herrick, M.D., Stella Herrick, A.T., Paul Ward, Ph.D.*

A. EQUIPPING THE POOL FOR MAXIMAL REHABILITATION BENEFITS

Practical application of aquatic exercise equipment

Water is a tremendous therapeutic medium for physical rehabilitation and conditioning. Throughout history, water has been used for relaxation, healing and exercise. The benefits were often met with suspicion because of unsupported and often extravagant claims regarding its healing powers. Gradually, however, water has become accepted as a valuable modality for physical rehabilitation whether following an injury, surgery or an "all-out" workout. In fact, the last decade has shown a significant increase in popularity of exercise and therapy in water. Health care professionals are becoming interested, educated and skilled in the field of aquatic therapy. There has also been an increase in aquatic facilities available for not only swimming, but for structured exercise classes and physical therapy. With greater understanding of the physical properties of water and the advantages of exercise in water, health care professionals, athletes, and coaches are encouraged to use the medium of water, making the most of its unique properties.

Water's physical properties alone provide an environment for exercises where there is little need for elaborate or expensive equipment. The property of buoyancy provides support and enables greater movement, making it possible to perform exercises which would be difficult, if not impossible, on land. Also often overlooked is the muscle strengthening and cardiovascular conditioning possible due to the resistance of the water. The water's resistance, the positioning of the limbs and body, the range of motion, the length of the lever arm, and the speed of the movements can all be used to increase the force or intensity of the exercise. However, the intensity can be further increased by the use of equipment designed specifically for water.

The emerging trend of aquatic therapy has brought about a new industry of manufacturers of exercise equipment designed exclusively for the water. This equipment, based on the physical principles of water, can offer needed support, increase the intensity of an exercise, add variety to a program, and make the exercise more challenging and enjoyable.

There are two basic classifications of aquatic exercise equipment. First are devices which utilize the effect of buoyancy to alter positioning or movement. Flotation devices are those items which increase the effect of buoyancy to provide support, decrease compressive forces or lessen impact, assist movement to the water's surface, and increase resistance in movement away from the water's surface.

Weighted equipment by contrast, decreases the buoyant effect. This is often useful in obtaining proper body position, providing stability for a patient/athlete, furnishing a means of traction, graduating compressive forces, assisting movement away from the water's surface and increasing resistance in movement toward the water's surface.

Using buoyant or weight equipment for resistance is particularly useful when trying to protect a joint from a specific motion or to isolate strengthening of a particular muscle group. Examples of this principle include protecting a sprained medial collateral ligament during standing straight leg hip abduction/abduction. With the use of an ankle weight, the leg can be abducted toward the water's surface with increased resistance. The weight then assists with abduction to protect the compromised ligament from possible stress due to the resistance of the water. Another example illustrates how to isolate strengthening of the hip abductors during rehabilitation of a

Chairman, United States Weightlifting Federation Sportsmedicine Committee

patient with a patella-femoral syndrome. Here a buoyant ankle cuff is utilized. This cuff assists standing hip abduction to eliminate strengthening of the lateral musculature, yet increases the resistance for hip abduction to strengthen the hip abductors for proper muscle balance and improved patellar tracking as for a subluxing patella (kneecap) or pattellofemoral syndrome.

The second basic classification of aquatic exercise equipment includes products which simply increase resistance by increasing the surface area that is pulled or pushed through the water. These devices are based on the principles of drag and movement through water. The larger the surface area, the greater the drag forces which increases the resistance. Also, these items can be moved in a streamlined pattern for decreased resistance or pattern for greater resistance and strengthening.

Most water exercise involves only concentric muscle contractions due to the resistance offered by any motion. This is also true using resistance equipment.

However, with buoyant equipment, eccentric muscle contraction can occur as the limb moves toward the surface of the water and the antagonists try to control the buoyant force. Eccentric contractions may also occur with the use of weight equipment as the antagonists control motion toward the pool floor.

Movement which is accustomed to gravity seems awkward upon entering the pool. Therefore, activities must be presented in such a manner that adjustments to the new environment are facilitated. The use of equipment for support and balance is essential during this adjustment period. Most aquatic exercise is performed with the participant standing in chest-deep water or working out in the deep end of the pool while using buoyant devices for support. There are many flotation devices which have been designed to keep the participant buoyant while working out in impact while working out in shallow water. The WET VEST, WET BELT and AQUA JOGGER are just a few examples of devices designed to float the exerciser in a vertical position, submerged to neck level so he/she can concentrate on performing the exercise correctly, rather than on treading water.

Styrofoam barbells, called SWIM BARS or TRAINERS are used for balance and support while gait training in shallow water as well as a flotation tool in deep water. They consist of a light weight bar with styrofoam ends, and utilize the principle of buoyancy. Swim trainers can also provide resistance for upper extremity rehabilitation strengthening exercises either before or in addition to progressive resistance exercises following an injury or corrective surgery.

A set of HYDRO-FIT equipment also capitalizes on the principle of buoyancy. The set includes buoyant ankle cuffs and buoyant barbells that are used for flotation and resistance of the upper and lower extremities. In addition, the ankle cuffs, when attached with one another, may be used as a flotation belt. This equipment is made from styrofoam and covered with a variety of colored nylon fabric.

Kickboards generally made of styrofoam, were designed as a swimming aid. Their use is once again based on the concepts of buoyancy and resistance. They can be used as flotation devices for lower body exercises or for increased resistance while running or strengthening the trunk and upper body muscles. The kickboard can be replaced by a disc-shaped piece of styrofoam called a WATER WAFER designed expressly for aquatic exercise. Other flotation devices which come in handy include neck supports and inner tubes. Inflatable neck supports are invaluable for comfortable support of the patient in the supine position in the water. Inner tubes of various sizes provide an inexpensive flotation device to support a patient off the bottom of the pool for non-weight bearing activities in deep or shallow water.

Weights which are used in the pool for traction or upper and lower extremity strengthening must be a type designed for water exercise. Most weights on the market are not suitable to use in the water since they will rust and cause staining of the pool surface and water chemistry imbalance. Many manufacturers of aquatic exercise equipment are now designing ankle and hand weights for pool exercise.

The types of equipment which are based on the concept of drag to produce resistance are as varied as buoyant equipment. Scuba fins and their benefits in increasing range of motion and strengthening of the ankle, knee and hip are not new to aquatic therapists. Manufacturers, however, are creating modern designs which differ slightly in mechanics. Examples of newer fins on the market include ZOOMERS, SLIM FINS, and FORCE FINS. WAVE WEBS were created for upper extremity strengthening based on the principle of increasing the surface area of the hand to produce greater resistance. They are snug fitting gloves made of colorful lycra material which have webbing between the fingers.

The AQUATONER is a resistance device which has three paddles or blades which can be adjusted to create a fan with variable surface area. The AQUATONER can be hand held for upper extremity exercises, or attached to the ankle or leg for lower extremity exercises.

One of the more unique types of aquatic resistance equipment on the market is the HYDROTONE SYSTEM. The system contains lower extremity boots and upper extremity bells which have a three-dimensional design. They are constructed from colorful hard plastic, and though buoyant, capitalize on the principle of resistance. The HYDROTONE equipment significantly increases drag, making any exercise more challeng-

ing.

A tether is a piece of equipment which is used for jogging or swimming in a small pool. A tether system involves rubber tubing that is attached to the participant by a belt around the waist and then held by the therapist or attached to the pool wall. The system will keep the athlete in place while running or swimming, and eliminate the constant need to change directions in a small pool. It may also be used to increase the intensity by increasing the force the subject is moving against.

Another item which athletes may use are aquatic shoes. These shoes are designed to be worn in the water to protect their feet from the bottom of the pool. The shoes will also increase drag, which will in turn increase the intensity of the workout. In addition they will provide better traction and prevent slipping.

Though water offers a unique medium with a natural resistance for exercise, equipment designed specifically for water can intensify the workout making it more challenging. The advantages of aquatic exercise include reduced pressure on joints while providing a medium to increase flexibility, muscular strength and endurance, proprioception, and cardiorespiratory fitness. Exercising in water is excellent for the injured, older, prenatal, and overweight individuals as well as the well-conditioned athlete. With the use of proper equipment, aquatic exercise can be more enjoyable and beneficial for the participant. As techniques in aquatic therapy advance, new equipment needs to be explored and developed based on the unique principles of water.

(Modified from article by C.S. Fuller, M.S., A.T., C., Sportsmed. Update Vol. 7 #2, 1992, by R.T. Herrick, M.D., F.A.A.O.S., F.A.C.S., F.I.C.S. and S.K. Herrick, A.T., C.Ped., O.P.A., O.S.T.)

B. WATERY WORKOUTS

By Paul Ward, Ph.D.

WALKING ON WATER: Nothing spiritual here, folks. Flotation devices let you walk or run through the water — assuming it's in the deep end of a pool—without the typical pounding of running on pavement

Belts and cuffs: A flotation belt provides you with enough buoyancy to walk or run without touching the bottom of the pool. Belts are superior to flotation vests for a simple reason—your body floats higher, enabling you to swing your arms freely for added momentum.

Inflatable flotation cuffs and foam cuffs—easily attached to your ankles and/or wrists—are another viable option: They keep your head and shoulders above water so you can run with strict vertical posture.

Training with a flotation belt or ankle cuffs for 20 to 45 minutes per workout (at 60 to 90 percent of your maximum heart rate) three times per week will give you a serious aerobic workout. But the cuffs also provide resistance—as much as three times the natural resistance of the water. The upshot is the ability to improve anaerobic (strength) fitness without risking injury due to the force of impact.

Aquatic-resistance equipment: The cuffs are one way to go for a watery pump, but you also have the choice of bells (much like dumbbells), boots (slip them on and just try to sprint at top speed), gloves (these Lycra models would work wonders for Michael Jackson) and buoys (again, much like a dumbbell designed for water use). All these products are designed to provide anaerobic and aerobic fitness benefits while either swimming, walking or running

THE AQUATIC-EXERCISE PRODUCT GUIDE: FLOTATION BELTS

AquaJogger by Excel Sports Science: 800-022-9544. Made of soft foam, the belt is adjustable, comfortable and comes in three colors: ocean blue, bright yellow, and pastel pink. It's easy to slip on and off. [AquaJogger EB for extra buoyancy.]

Hydro-Belt by Hydro-Tone International: 800-622-8663. Made of coated, insulated foam, the belt has two straps to ensure a tight fit. It floats you in the water at shoulder depth and provides back support, much like a weight belt. The insulation in the foam will keep your back warm - even in cold water- during a workout.

Water Walker by J & B Foam Fabricators: 800-621-3626. A nylon strap with four closed-cell foam floats attached, the device is designed to keep you buoyant and stable during deep-water running and aerobics.

Wet Belt by Hydro-Fit: 800-346-7295. A soft belt (made of a substance similar to neoprene) that tapers to your physique with an easy-to-adjust Velcro waistband adding comfort; the design provides stability, safety and support.

RESISTANCE EQUIPMENT

Inflatable Ankle and Wrist Cuffs by Fitness Research of Southern California: 310-547-5793. Both are air inflated devices made of polyvinylchloride (PVC) that slip on easily. The ankle cuffs provide buoyancy while tripling water resistance as you run, walk or swim. Wrist cuffs add an upper-body toning emphasis. An optional air pump (to inflate the cuffs)

is available.

Hand Bar by J & B Foam Fabricators: 800-621-3626. It's a 12-inch tube with a 2 1/2 inch piece of foam on either end that you grasp much like a barbell. This device allows you to do curls, arm raises and other resistance exercises.

Hand Buoys by Hydro-Fit: 800-346-7295. Foam dumbbells with a cushioned hand grip, they let you perform any upper-body exercise you can do in the gym with a dumbbell. The buoys also allow you to float in deep water if you're too pooped to keep pumping.

Hydro-Bells by Hydro-Tone International: 800-622-8663. Hand-held devices resembling the shape of a Chinese lantern, the bells create added resistance in water, regardless of the direction in which you're moving. The faster you swim or run, the greater the increase in resistance. Double your speed, for example, and you'll quadruple your resistance.

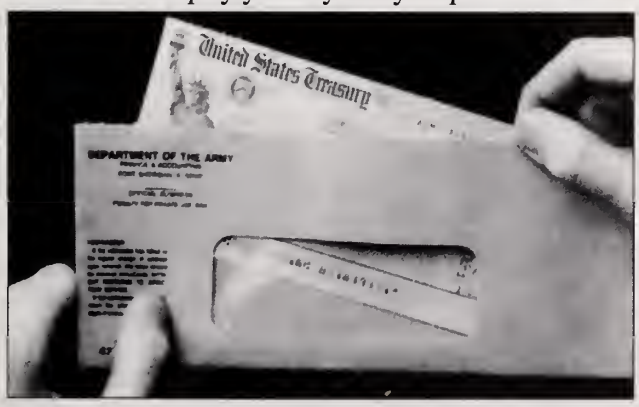
Hydro-Boots by Hydro-Tone International: 800-622-8663. These unusual snap-ons look like the top half of a ski boot-with wings attached. (The wings are actually plastic fins that trap water to create resistance as you move.) Great for adding resistance to running strides, karate kicks, lateral strokes and circular motions.

Sprint Bells and Sprint Water Gloves by Sprint/Rothhammer: 800-235-2156. The bells are made of water foam; again, you can do any basic dumbbell exercise using this device. The neoprene/Lycra gloves (available in small, medium and large) work the same way as the Wave Web gloves by Hydro-Fit.

Wave Webs by Hydro-Fit: 800-346-7295. These Lycra gloves increase the resistance of almost any water sport—swimming, surfing, scuba and water aerobics, to name a few—by giving you more water to pull with each stroke. They're available in six colors (they double as a fashion statement) and three sizes.

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Newborn Cogential Anomalies in Jefferson County, Alabama

Wayne H. Finley, Ph.D., M.D.; Tracy M. Hall, MS; David C. Hurst, Ph.D.: Sara C. Finley, M.D.; Edward D. Conner, M.D.; Clyde M. Bargainer, DrPH; JoAnn Weidmeyer, BSN.

Introduction:

Congenital anomalies have become a leading cause of infant morbidity and mortality in this country and those newborns affected require significant health resource.[1,2] Studies of frequencies of congenital anomalies have often been retrospective and have relied upon multiple sources such as birth certificates and hospital records. In 1985 the Jefferson County Medical Society organized a surveillance program to monitor all hospital births and to document congenital anomalies observed in infants born in Jefferson County, Alabama, during a 2-year period. This prospective study was undertaken with cooperation of the 11 hospitals with delivery services, and anomalies were recorded by a single maternal and child health nurse. The computerized data base generated would be available to estimate health resources required for management, provide information for follow-up of affected infants, possibly detect sudden changes in birth defect incidences, and to help identify research directions for prevention of birth defects. Some of these data have been reported. [3,4]

Methodology

A survey of all newborns of 20 or more weeks gestation was conducted in Jefferson County, Alabama hospitals for a 2-year period (January 1, 1986-December 31, 1987). Information about infants noted to have a congenital anomaly was obtained weekly at the hospital of birth, and 99.7% of births occurred in or en route to one of the 11 hospitals.

The study group consisted of 27,904 births of which 27,561 were live-born. Of the live-born infants 65% were white and 35% were non-white (black). The same nurse reviewed delivery records, examined affected infants if possible, and obtained autopsy reports to complete the data sheet. The minimum data recorded were birthdate; birth weight; sex; gestational age; discharge status: maternal race, age, parity and zip code; and hospital of birth. Code numbers were assigned the observed congenital anomalies in accordance with the International Classification of Disease (ICD).

Results

The number of births in Jefferson County during 1986-1987 represented 23.5% of the total births in Alabama (Table 1). The total white births in the county were 18,081 (23.3% of the State's white births) and the total non-white births were 9,823 (23.7% of the State's non-white births).

Some comparisons of data in Tables 1-5 are:

Non-white stillbirths (17.2/1,000) > white stillbirths (9.6/1,000) ($p<.0001$)

Non-white male stillbirths (17.7/1,000) > white male stillbirths (11.3/1,000) ($p<.0001$)

Non-white female stillbirths (16.7/1,000) > white female stillbirths (7.8/1,000) ($p<.0001$)

Non-white births with congenital anomalies (25.8/1,000) > white births with congenital anomalies (22.4/1,000) ($p< .01$)

Non-white livebirths with congenital anomalies (23.9/1,000) > white livebirths with congenital anomalies (19.0/1,000) ($p<.002$)

White male livebirths with congenital anomalies (24.5/1,000) > white female livebirths with congenital anomalies (13.3/1,000) ($p<.0001$)

Non-white male livebirths with congenital anomalies (27.2/1,000) > non-white female livebirths with congenital anomalies (20.5/1,000) ($p<.002$)

White stillbirths with congenital anomalies (2.2/1,000) = non-white stillbirths with congenital anomalies (2.2/1,000)

Anencephaly in white livebirths (2.3/10,000) > anencephaly in black livebirths (1.0/10,000) ($p<0.01$)

Spina bifida in white livebirths (15.0/10,000) > spina bifida in black livebirths (9.3/10,000) ($p<0.01$)

Hypospadias in white male livebirths (31.6/10,000) > hypospadias in black male livebirths (24.6/10,000) ($p<0.0003$)

Polydactyly in black livebirths (118.1/10,000) >

From the Laboratory of Medical Gentics, Department of Pediatrics (Drs. Finley and Miss Hall), Department of Biostatistics and Biomathematics (Dr. Hurst), University of Alabama at Birmingham, Birmingham; St. Vincent's Hospital, Birmingham (Dr. Conner), Alabama State Department of Public Health, Montgomery, Alabama (Dr. Bargainer); Jefferson County Medical Society, Birmingham, Alabama (Ms. Wiedmeyer). Reprint request: Wayne H. Finley, PhD, MD, UAB, Birmingham, AL 35294.

Table 1. Jefferson County, Alabama Births (1986-1987)

Category	All Births No.	%	Live Births No.	%	Stillbirths No.	%	Frequency (10^3)
White Male	9,248	33.3	9,179	33.3	105	30.6	11.3
White Female	8,797	31.5	8,728	31.7	69	20.1	7.8
Total White Births	18,081	64.8	17,907	65.0	174	50.7	9.6
Non-White Male	4,971	17.8	4,883	17.7	88	25.7	17.7
Non-White Female	4,852	17.4	4,771	17.3	81	23.6	16.7
Total Non-White Births	9,823	35.2	9,654	35.0	169	49.3	17.2
Total Births	27,904		27,561		343		12.3

Total Alabama Births (1986) 59,441 (Whites 38,632: Others 20, 809)[5]
Total Alabama Births (1987) 59,558 (Whites 38,826; Others 20,732)[6]
Total Alabama Births (1986, 1987) 118,999 (Whites 77,458; Others 41,541)

Table 2. Number of Newborn Infants with Congenital Anomalies in Jefferson County, Alabama (1986-1987)

Category	All Births (Affected) No.	%	Frequency (10^3)	Live Births (Affected) No.	%	Frequency (10^3)	Stillbirths (Affected) No.	%	Frequency (10^3)
White Male	225	38.8	27.5	225	39.3	24.5	17	27.4	1.8
White Female	150	22.8	17.1	116	20.3	13.3	22	35.5	2.5
Total White Births	405	61.6	22.4	341	59.6	19.0	39	62.9	2.2
Non-White Male	145	22.0	29.2	133	23.3	27.2	10	16.1	2.0
Non-White Female	108	16.4	22.3	98	17.1	20.5	8	12.9	1.6
Total Non-White Births	253	38.4	25.8	231	40.4	23.9	22*	35.5	2.2
Total Affected	668*	23.9	572	20.8	62*				

*Status unknown for 10 affected infants

Table 3. Congenital Anomalies in Live Born Infants (per 10,000 births)

	This Study (1986-1987)	Atlanta[7] (1967-1968)	U.S.A.[1] (1981-1986)
Anencephaly			
White	2.3	10.6	3.0
Blacks	1.0	1.4	2.1
Spina Bifida			
Whites	15.0	17.5	5.1
Blacks	9.3	9.8	3.3
Hydrocephalus			
Whites	15.6		5.4
Blacks	14.5		8.1
Cleft Lip/Cleft Palate			
Whites	14.0	11.1	15.6
Blacks	10.4	4.2	8.1
Heart Malformations			
Whites	16.8	22.8	50.7
Blacks	14.5	22.4	77.7
Club Foot			
Whites	14.5	31.8	27.5
Blacks	11.4	25.2	19.9
Hypospadias			
Whites	31.6		32.7
Blacks	24.6		24.6
Polydactyly			
Whites	14.5	11.7	
Blacks	118.1	93.9	
Down Syndrome			
Whites	11.2		8.5
Blacks	8.3		6.5

Table 4. Incidences of Specific Congenital Anomalies in Maternal Age Groups for Jefferson County, Alabama (1986-1987)

Rate (10^3)	All Ages	<15	15-19	20-24	25-29	30-34	35-39	>40
Total Anomalies	23.9	15.3	24.4	25.9	20.3	22.8	31.5	16.8
Anencephaly	0.5		1.8	0.2	0.3			
Spina Bifida	1.3		2.3	1.7	1.0	0.6	1.3	
Hydrocephalus	1.5		2.3	1.4	0.9	0.8	2.6	
Cleft Lip/ Cleft Palate	1.7		1.1	0.9	1.9	2.3	0.6	
Omphalocele	1.0		1.3	1.7	0.8	0.8	0.6	
Heart Malformations	2.2		1.5	2.3	1.1	2.8	5.1	5.6
Club Foot	1.6		2.5	1.6	1.3	2.5	1.9	
Hypospadias	2.9		1.5	2.6	1.3	0.9	1.3	
Polydactyly	5.0	7.6	5.3	5.3	3.0	3.2	3.2	
Syndactyly	1.0		1.3	1.2	1.1	0.6	0.6	
Down Syndrome	1.3		0.3	0.6	2.3	8.3	5.6	

Table 5. Incidence (10^4) of Congenital Anomalies in Liveborn Infants in Jefferson County, Alabama and Projections for Alabama*

	Frequency (Jefferson Co.) 1986-1987			Number Suspected (Alabama) (1986-1987)		
Anencephaly		M	F		M	F
Whites	2.3	1.1	3.4	17.8	4.4	12.8
Blacks	1.0	2.0	0.0	4.2	4.2	0.0
Spina Bifida						
Whites	15.0	12.0	18.3	116.3	47.6	69.0
Blacks	9.3	12.3	6.3	38.6	25.9	13.0
Hydrocephalus						
Whites	15.6	17.4	13.7	120.9	69.0	51.7
Blacks	14.5	14.3	14.7	60.2	30.1	30.3
Cleft Lip/ Cleft Palate						
Whites	14.0	16.3	11.5	108.5	64.6	43.4
Blacks	10.4	12.3	8.4	43.2	25.9	17.3
Heart Malformations						
Whites	16.8	22.9	24.1	130.2	90.7	90.9
Blacks	14.5	20.5	18.9	60.2	43.2	38.9
Club Foot						
Whites	14.5	21.8	6.9	112.4	86.4	26.1
Blacks	11.4	18.4	4.2	47.3	38.8	8.6
Hypospadias						
Whites	31.6	31.6		244.9	125.2	
Blacks	24.6	24.6		103.1	51.8	
Polydactyly						
Whites	14.5	22.9	5.7	112.4	90.7	21.5
Blacks	118.1	124.9	111.1	490.1	263.1	228.7
Down Syndrome						
Whites	11.2	15.2	6.9	86.8	60.2	26.0
Blacks	8.2	6.1	10.5	34.4	12.8	21.6

*Based on combined 1986-1987 data

White births	77,458
Black births	41,541
White male births	39,627
White female births	37,723
Black male births	21,063
Black female births	20,587

polydactyly in white livebirths (14.5/10,000) ($p>0.0001$)

Specific malformation incidences which did not differ significantly in white and black livebirths were hydrocephalus, cleft lip/palate, heart malformations, and club foot. The higher anomalies in stillborn white female infants (2.5/1,000) was accompanied by the lowest incidence of anomalies in liveborn white female infants (13.3/1,000).

The incidence of affected infants with younger non-white mothers was higher than in those with older white mothers (Table 6). A higher percent of non-white mothers were teenage than were white mothers. The birth rates in white mothers were higher beginning with the 25-29 age group and in black mothers in the 2024 age group.

Table 6. Births and Affected Births in Maternal Age Groups.

Maternal Ages	<15	15-19	20-24	25-29	30-34	35-39	>40
Births (%)							
White	0.1	10.5	27.6	34.3	20.8	6.1	0.6
Non-white	1.1	20.8	31.8	25.7	15.3	4.7	0.6
Combined	0.5	14.1	29.1	31.2	19.0	5.6	0.6
Affected(%)							
White	0.2	13.2	29.4	27.6	19.9	9.2	0.2
Non-white	0.4	16.9	36.2	25.6	15.7	4.7	0.4
Combined	0.3	14.6	31.9	26.9	18.4	7.4	0.5

Approximately 10% of the total newborns weighed < 2,500 grams and in this group were 28% of the affected infants (Table 7). The majority of both white and non-white infants weighed between 3,0013,500 grams, however, 40% of white infants and only 22% of nonwhite infants weighed more than 3,500 grams. A total of 7% and 14% of white and black newborns respectively weighed < 2,500 grams.

Discussion

A prospective study to determine the incidence of congenital anomalies in newborn infants in Jefferson County, Alabama was undertaken to gain experience in birth defects surveillance and to provide estimates of statewide occurrence rates. This study was encouraged by the Maternal and Child Health Committee of the Jefferson County Medical society and the 11 Jefferson County hospitals with obstetric services. Data concerning the types and patterns of occurrence of congenital anomalies, a leading cause of infant morbidity and mortality, would aid in planning for health

Table 7. Birth Weight of Resident Infants in Jefferson County, Alabama (1986-1987)*

Birth Weight (gm)	White Births		Non-White Births		Total Births	
	No. Affected	(%)	No. Affected	(%)	No. Affected	(%)
<1,000	0.7	10.5	1.9	6.9	1.2	8.9
1,000-1,500	0.6	4.1	1.6	4.9	1.0	4.3
1,501-2,000	1.2	6.9	2.8	4.5	1.9	5.7
2,001-2,500	4.5	8.8	8.1	10.5	6.1	9.3
2,501-3,000	16.1	19.9	25.8	19.4	20.4	19.3
3,001-3,500	36.3	22.9	38.1	30.8	37.1	25.4
3,501-4,000	28.9	20.2	17.4	19.0	23.8	19.3
4,000-4,500	10.0	9.4	4.0	3.6	7.3	6.9
>4,501	1.6	1.4	0.6	0.4	1.1	1.0

*Birth weights of resident births, not of those delivered in Jefferson County hospitals with residences outside.

resources. Occurrence rates in Jefferson County, Alabama's most populous county, determined over a 2-year period, gave an opportunity to estimate number of affected infants statewide.

Distribution of specific congenital anomalies is known to differ on the basis of ethnic groups, sex, and geography[1,8,9]. It is recognized that some differences might be accounted for by variation in clinical methodology and system of recording. Differences between Alabama data and other locales could reflect gene pool differences, environmental conditions, cultural influences, access to medical care, nutrition, alcohol consumption, and other socioeconomic factors. An extension of this study would be collection of data from more rural and less industrialized areas of Alabama for comparison with Jefferson County information. significant differences in incidences could result in specific research projects and in better planning for management of patients. Some variation in the number of affected infants between widely scattered geographical areas have been reported in many studies, however, a greater variation has been noted for selected anomalies.[10-12]

The newborn population of Jefferson County (Table 1) provided a good opportunity to compare congenital anomalies in whites with non-whites (blacks). Previous studies have shown that black infants had a higher overall frequency of congenital anomalies than whites, however, this higher incidence in blacks could be attributed to an increase in minor malformations. Our study (Table 2) showed a higher incidence of affected black infants (25.8/1,000) to whites (22.4/1,000) while the national frequency was lower than both (19.7/1,000). The 2-fold increase in low birth weight infants in the non-white group over the whites occurred without an appreciable difference in percent affected with congenital anomalies.

Differences in frequencies of congenital anomalies in males and females have been reported in several studies.[15,16] Our data indicated a higher frequency of affected white males (24.5/1,000) to white females (13.3/1,000) and higher affected non-white males (27.2/1,000) to non-white females (20.5/1,000). The high frequency of anomalies (35.5/1,000) in white female stillborn infants is unexplained.

Incidences of specific anomalies differ between ethnic groups. studies have shown that infants with multiple anomalies occur with about the same frequency in whites and blacks.[14] In our study the occurrence of stillborn infants was higher in the black group than in the white group; higher in black males than white males; and higher in black females than white females. Occurrence of stillborns with congenital anomalies was the same in black and white infants, therefore, the significant differences in black and white stillborn incidences are not explained by observable congenital anomalies. White stillborn female infants with congenital anomalies occurred at a higher incidence than either white male, black female, or black male stillbirths.

Neural tube defects, being one of the most common congenital anomalies, is now receiving much attention because of the finding that preconceptual folic acid can affect the rate of occurrence.[17-19] Our data may be very important for comparison later to recorded incidences after folic acid becomes widely used before and during pregnancy. Findings of a higher incidence of anencephaly and spina bifida in white liveborn infants would justify study of dietary folic acid in both white and black mothers. Higher incidences of neural tube defects in white infants than in black infants were reported in the 1967-1968 Atlanta Study[1] and in the 1981-1986 USA study, both of which showed higher frequencies than in an Asian population[7]. At this time it is not known to what extent prenatal detection programs in this country and others, have effected the occurrence of neural tube defects in liveborn infants.[12] Increased recurrence risks have placed neural tube defects into the multifactorial group of genetic disorders, realizing that there are both geographical and ethnic group variations in incidences.

The incidences of specific congenital anomalies occurring in the various maternal age groups are tabulated in Table 4. Incidences for specific anomalies were

about the same for various age groups except for heart malformations and Down Syndrome which had higher incidences in mothers above 35 years of age.

Some fluctuation can be expected in a particular geographical area, however, estimates of congenital anomaly incidences periodically could be useful for research, design of services, planning for personnel requirements, and determining the burden on families with affected members. The baseline data could be useful for various Specialists and Rubspecialists who manage patients with congenital anomalies. A monitoring system would permit early detection of an epidemic of a rare malformation, ascertainment of gradual changes in incidences of common malformations, and design of research to evaluate genetic and environmental contributions to specific malformations. Particularly the medical genetics teams in formulating future plans could use these data in designing education materials for primary health providers and for reaching those Alabama families needing genetic information.

Our data were compiled economically and the procedures used could be taken ag a pilot study for expansion to a regional or statewide surveillance program. Bxperienced personnel have the opportunity to collect valuable health data in newborn nurseries. A continuing surveillance program would be valuable to many who deal with prenatal care, poor pregnancy outcomes, recurrence risks, patient management, family counseling and follow-up.

Newborn screening information already being collected added to a registry of congenital anomalies would be helpful in establishing statewide priorities in health planning. Specialized clinical and laboratory genetic services continue to offer preventive approaches which can reduce health costs and contribute to easing the family burdens. Surveillance for congenital anomalies in infants and children will give data important for the planning of health care reform measures.

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Colorectal Cancer Hepatic Metastases: The Surgeons Role

Charles R. Shumate, M.D.

INTRODUCTION

Colorectal carcinoma will affect an estimated 149,000 persons in 1994. Half of these patients will develop recurrent disease yielding 56,000 deaths, making colorectal cancer the second leading cause of cancer-related deaths in the United States.[1]

The primary site of recurrence is the liver which is involved in 70% of recurrences and is an isolated site of recurrence in 15 to 20% of cases. Contrary to established dogma, patients with isolated hepatic metastases have the potential for long-term survival with appropriate therapy.

PROGNOSIS

A common misconception is the rapid and uniformly fatal outcome of liver metastases. Reported overall survival rates vary from 6 to 18 months, however, a significant number of patients will survive for a longer interval. The most important predictive variables of survival are extent of hepatic replacement, performance status, and extrahepatic disease.[2]

The extent of liver replacement can be determined by several methods. The simplest, and probably most reproducible, is the number of metastases. The median survival for patients with less than 3 or 4 metastases is 24 months or 40 to 50% at 2 to 3 years. A palpable liver or elevated liver function tests indicates more extensive disease and predicts a median survival of 6 to 12 months. Performance status estimates patients' overall function in the presence of cancer. Asymptomatic patients, performing daily activities without restriction, have a median survival of 18 months. As symptoms increase the median survival will dramatically decrease to 6 months or less. Extrahepatic recurrence indicates widespread tumor dissemination which is not amenable to surgical treatment or regional chemotherapy. The median survival for these patients is around 9 months. Despite the presence of extrahepatic tumor, greater than 85% of these patients will die with or of hepatic failure.

Therefore, a subpopulation of patients with liver metastases exists which has a more favorable prognosis. This may represent more biologically favorable tumors, but few of these patients will experience long-term survival without therapy.

TREATMENT

No single modality has yet acquired widespread acceptance for treatment of colorectal cancer hepatic metastases. This is due in part to frequent occult extrahepatic metastases, heterogeneity of colorectal tumors, and a lack of randomized prospective therapeutic trials. Thus systemic chemotherapy, regional chemotherapy, surgical resection, cryotherapy, and alcohol injection all have proponents and undeniable advantages and disadvantages. Improved patient outcome will not result from one modality but instead a carefully integrated multimodality approach.

SYSTEMIC CHEMOTHERAPY

Systemic chemotherapy is logical for colorectal cancer hepatic metastases since most patients have other sites of recurrence, often occult. The fluoropyrimidines, especially 5-fluorouracil (5FU), have the greatest activity against colorectal cancer and are the mainstay of chemotherapeutic agents.

5-FU alone provides response rates of less than 20% and is often combined with a modulating agent, usually leucovorin. The two drugs in combination yield response rates of 16 to 45 depending on the dose and method of delivery. Nonetheless, complete responses are rare and duration of response is usually short. Systemic toxicity is common, reportedly occurring in 50 to 60% of patients.[3]

Systemic chemotherapy's lack of durable response, toxicity, and few long-term survivors maintains interest and investigation of regional chemotherapy and surgical resection.

HEPATIC ARTERY INFUSION CHEMOTHERAPY

Hepatic metastases derived their blood supply from the hepatic artery while normal hepatocytes are predominantly supplied by the portal vein. Chemotherapeutic agents with a high hepatic extraction given via the hepatic artery are attractive since systemic toxicity should be reduced and tumor response increased. Fluorouracil (5-FU) and Floxuridine (FUDR) have high hepatic extraction (80 and 95% respectively) and activity against colorectal cancer.

Hepatic artery infusion therapy began in the 1960's with percutaneous access. Response rates have varied depending on tumor volume, presence of extrahepatic disease, chemotherapeutic agents, and method of assessment. Response rates of 30 to 80% have been reported, however, more recent studies using computerized tomography assessment demonstrates major (complete and partial) response rates of approximately 50% and median survival of 16 to 22 months.[4-9]

Development of the totally implantable pump in the early 1980's obviated many of the problems incurred with the original transfemoral or transaxillary approach. Arterial complications due to repeated cannulations do not occur and catheter and pump related problems are virtually nonexistent. Chemical cholecystitis and duodenitis has been eliminated with cholecystectomy and careful devascularization of the gastroduodenal and common hepatic arteries. Systemic toxicity is rare since 5-Fluorouracil and FUDR are almost completely extracted by the liver.

Cost, lack of a proven survival advantage and biliary toxicity has limited the widespread use of hepatic artery infusion pumps for hepatic metastases. Until recently this form of therapy was associated with a high rate of bile duct sclerosis which limited the duration of treatment. 30 to 40% of patients treated with high dose FUDR (0.3 mg/kg) will develop biliary toxicity, initially manifested as alkaline phosphatase elevation, requiring dose reductions or cessation of therapy.[4-9] Combining 5-Fluorouracil and FUDR (0.1 mg/kg) seldom results in biliary toxicity and thus allows prolonged duration of treatment.[6] (Table I) Response rates with the combination regimens are equal to the higher FUDR regimen and a survival advantage may now be seen with hepatic artery infusion therapy over systemic therapy.[6] In fact, median survival with this regimen is 22.4 months, which is longer than the 16 to 17 months reported in other trials.

Table I
RESPONSE AND TOXICITY
vs. FURDR DOSE

Response Rate*	**FUDR****	**FUDR*****
Major	42%	50%
Minor	22%	15.6%
Stable	20%	15.6%
Progressive	16%	18.8%
Biliary Toxicity	52%	0%

*Major: ≥ 50% reduction of perpendicular diameter of tumor by CT; Minor: 25-50% reduction; Stable: no change; Progressive: enlargement

**FUDR: 0.3 mg/kg/day (Ref 7)
***FUDR: 0.1 mg/kg/day; 5-FU, 15 mg/kg sideport bolus (Ref 6)

Four randomized prospective studies have evaluated hepatic artery infusion chemotherapy vs. systemic chemotherapy.[5,7,8,9] Executing a perfect clinical trial with hepatic metastases is difficult due to problems associated with patient selection, accurate randomization, and accrual. The evaluation of intraarterial chemotherapy vs. systemic chemotherapy has been further hampered by crossover arms in all but one trial. Thus all, but the French study[9], have not demonstrated a survival advantage for intra-arterial chemotherapy. Additionally these studies usually employed the higher FUDR dose, therefore many patients developed biliary toxicity causing a reduction or cessation of intra-arterial treatment. If the other studies are evaluated with consideration of the crossover arm, then intra-arterial therapy does show a survival advantage over systemic chemotherapy as seen in Table II. While survival data is difficult to interpret due to small study size and crossover arm provisions, a better response rate with intra-arterial therapy is undeniable. (Table II).

Table II
RESPONSE AND SURVIVAL RATES (%)
SYSTEMIC vs. HEPATIC ARTERY INFUSION

	MSKCC (Ref 8	**NCOG** (Ref 7)	**NCI** (Ref 5)	**FRENCH** (Ref 9)
Response		**FUDR****		**FUDR*****
Systemic	20	10	17	14
H A I*				
Survial				
Total				
Systemic	20	20	13	10
H A I*	25	30	44	22
Excluding Crossover				
Systemic	14	17	-	10
H A I*	25	40	-	22

*Hepatic Artery Infustion

Hepatic artery infusion therapy via an implantable pump provides better tumor response, less systemic toxicity and possibly improved survival over systemic therapy. The pumps cause little inconvenience to the patient and physician when meticulous attention is directed to technical details intraoperatively and with proper care postoperatively. Hepatic artery infusion therapy is not the panacea for unresectable liver metastases but it may provide the best balance of tumor control and quality of life.

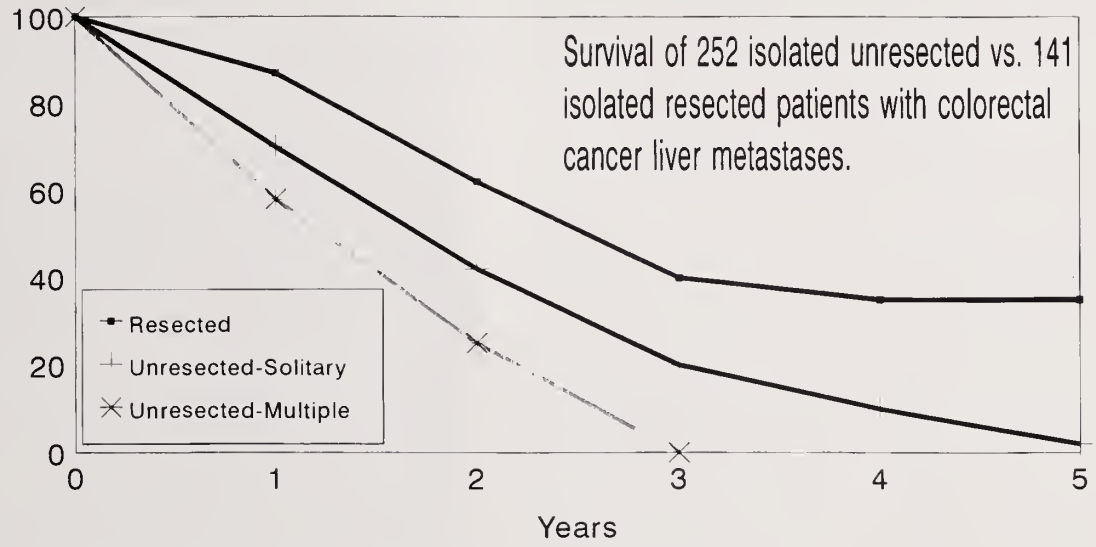
SURGICAL RESECTION

Unresected hepatic metastases are ultimately fatal. Wagner et al[10] demonstrated superior survival of patients with resected metastases over comparable patients without resection. (Fig 1) Whether better sur-

Colorectal Carcinoma

Hepatic Metastases

Survival



Adapted from Wagner, et al: Annals of Surgery, 1994.

FIGURE 1

vival is related to the natural history of biologically favorable tumors or the impact of resection is debatable and yet unproven.[9] Since hepatic resection from metastases has a low operative morbidity and mortality (Table III) and effective systemic chemotherapy is not available, appropriate candidates should be offered surgical resection of hepatic metastases from colorectal cancer.[11] The most important issues involve proper patient selection for resection and avoidance of recurrence.

Table III
SURGICAL RESECTION HEPATIC METASTASES
PATIENT SELECTION CRITERIA

Morbidity	10-25%
Mortality	< 5%
Survival:	
5-Year	25 - 45%
Median	24 - 37 mos.

A multi-institutional review provides insight into selection criteria for resection.[12] The presence of positive hepatic nodes, extrahepatic metastases, or more than 4 hepatic metastases should be a contraindication to resection. There are no 5-year survivors with extrahepatic tumor and few patients with more than 4 hepatic metastases will survive for 5 years. Factors having a negative influence on survival but not a contraindication to resection are margins less than 1 cm, Dukes C primary, and a disease free interval of less than one year. (Table IV)

Table IV
SURGICAL RESECTION HEPATIC METASTASES
PATIENT SELECTION CRITERIA

Absolute Contraindications	Relative Contraindications
> 4 metastases	Margins < 1 cm.
Hepatic nodal metastases	Node positive primary
Extrahepatic metastases	DFI* < 1 year

DFI = Disease Free Interval

Surgical resection is safe and offers the best hope for long term survival, however, up to 40% of patients will recur in the liver and another 20 to 40% will recur in extrahepatic sites. Thus, combining surgical resection with effective chemotherapy may have some benefit. Previous studies have not proven a benefit for systemic chemotherapy after hepatic resection. However,

a recent pilot trial noted 50% reduction of expected hepatic recurrence with regional 5FU[13] and clinical trials are underway further evaluating post-resection intra-arterial and/or systemic chemotherapy.

SUMMARY

Liver metastases are not uniformly fatal. A group of patients exists that will benefit from therapy directed at the liver either with surgical resection, intra-arterial chemotherapy or a combination of both.(Fig 2) All patients should be evaluated for the possibility of surgical resection since it can provide a 5-year survival of 25 to 40%, or hepatic arterial infusion therapy since response rates are higher and toxicity lower than systemic chemotherapy.

When metastases are discovered simultaneously with the primary tumor, consideration should be given to concomitant treatment of both the primary and the liver if the patient is a suitable operative candidate and the resection will not entail more than a wedge or a left lateral lobe resection. Metastases discovered on follow-up of the primary tumor may be immediately addressed with surgical resection or hepatic artery infusion pump placement if the disease-free interval has been greater than 1-2 years. When the disease free interval has been less than a year, systemic chemotherapy is probably more prudent to allow time for manifestation of extra hepatic disease. If no extrahepatic metastases become manifested after 6 months of systemic chemotherapy, then regional chemotherapy or resection should be considered. Intrahepatic progression on systemic chemotherapy is not a contraindication to hepatic artery infusion chemotherapy since the metastases may still respond. This approach allows patients manifesting extrahepatic disease while on systemic chemotherapy to be spared an operative procedure.

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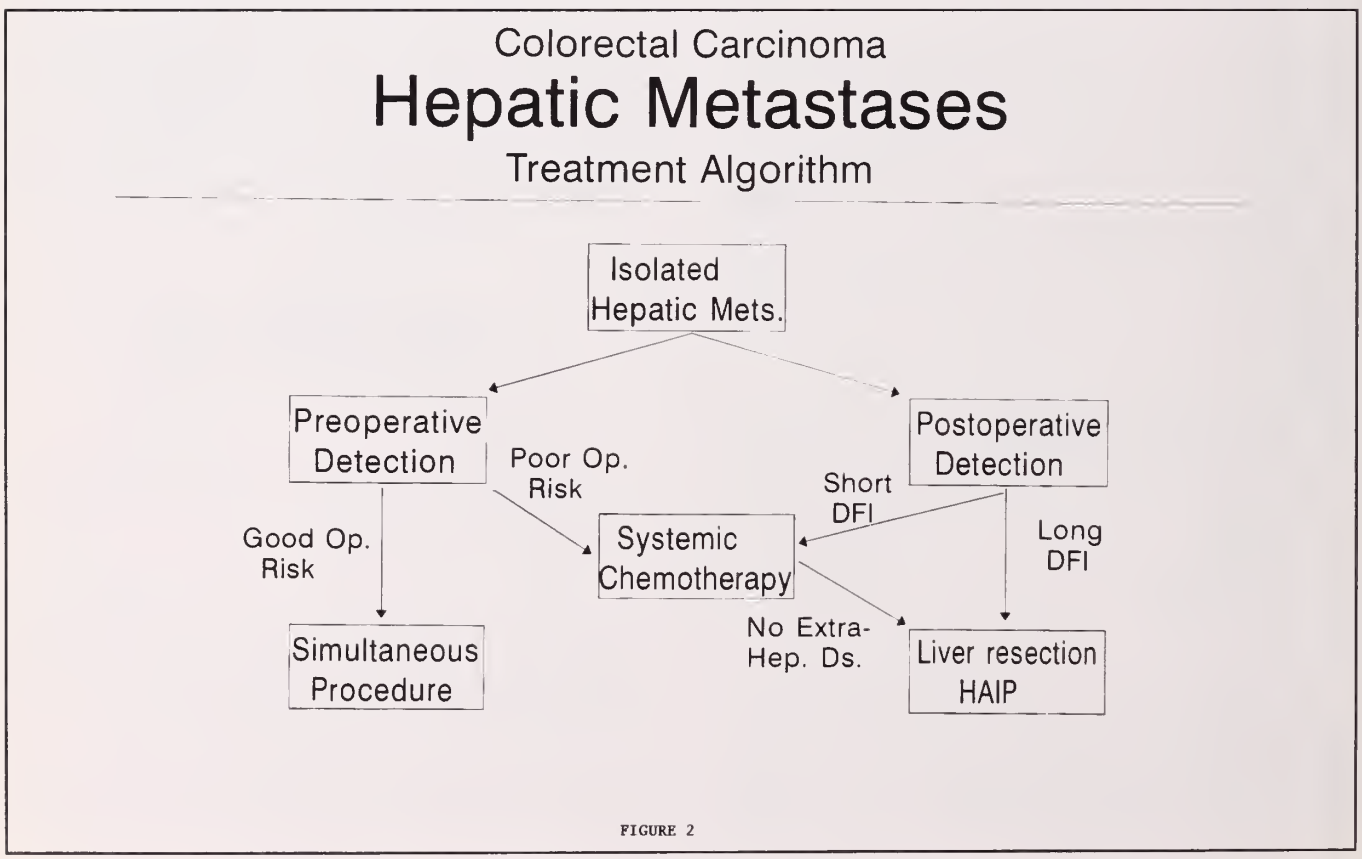


FIGURE 2

Confessions of a 'High–Bottom' Drunk

A Physician's Story of Addiction & Recovery

By Gerald L. Summer, M.D., Medical Director, Physicians' Recovery Network, (PRN)

The following saga is true. The author is currently a successful recovering physician in Alabama who wishes to remain anonymous. His story of chemical dependency in physicians is not atypical. A successful sub-specialist, he never experienced quality care issues nor patient complaints, was never divorced nor arrested, and felt like he was a good doctor. However, his self-image was in question as manifested by grandiosity and constant efforts at seeking the approval of others. Because of his unconscious distortion of reality and denial, he was unable to relate his drinking to consequences – being "kicked out of the country club twice..." and "blaming other people for may personal problems." Progression of the disease resulted in self-administration of Xanax and changing schedules to accommodate alcohol use. Treatment began with fears, which later in recovery, were proven to have no valid basis. The narration also illustrates positive progress in recovery by resolution of the denial process – "I knew in my heart... that I indeed was an alcoholic." Assuming responsibility for one's own actions and learning to "live happily without the crutch of alcohol" indicates acceptance of his disease. Finally, a positive self-image develops and true family recovery begins.

"It was a beautiful brisk fall day that third weekend in October of 1991. The night before I had been out all night drinking and partying because I'd come into four tickets for the Tennessee/Alabama football game. I'm not sure what happened that night. I passed out at home, and the next morning got up at 7:30 with the shakes, went by Hardee's got me a 7-Up and poured my first drink of the day on the way to the Tennessee/Alabama football game.

"As I remember, the start of the game that day was very early for national TV – around 11:30. I got to the Legion Field area about 9:30 or 10:00 after having consumed about a half a pint of whiskey on the way and began to hit the bars that are so famous around Legion Field. I know that Alabama won the game that day. Being new to the area and everybody being for Alabama, I wanted to be for Tennessee. I remember sitting in the end zone and taking my shirt off like a lot of the 19-year-olds, although I was a 45-year-old, overweight, gray-haired physician. I left in the third quarter and got a drink at the bar.

"The last thing I remember was the day saying 'You don't have a hair on your a_ _ if you don't drink a double Crown Royal and water.' So down the hatch it went, into my Cadillac I got, and on the way to the Winfrey Hotel I was determined to out-drink everybody there. I began calling the emergency room telling them that I could not work that night. I even tried to call the chief operating officer of the hospital to tell him that I wasn't coming in. I don't really remember leaving the Winfrey parking lot. I do remember I left the bar with two drinks in my hand, got in my car and ran the gate.

"Not remembering anything of the drive, I arrived home and passed out, only to get up and brush my teeth, try to eat some food, and showed up at the emergency room an hour late. Shortly after arriving for emergency room duty I fell asleep and was relieved from my duties about 10:00 by an ER physician who came in and said he didn't think I could finish. I went home scared and nervous and came back the next day to try to cover my tracks. He looked irritated but said nothing.

"Three days later I was in the administrator's office with Dr. Gerald Summer, my lawyer, and the lawyer for the hospital's liability insurance carrier. I am convinced until this day that our chief operating officer, because of some things that had happened in the past, wanted to really put the screws to me, but maybe I had to have that done. Thank goodness for the Physicians Recovery Network, for if they had not been there, maybe this would have happened. I went to evaluation, got assessed, the diagnosis of alcoholism was made, and I went back for another thirty days. I have been in a recovery program and have not had a drink since October 1991.

"But not let's step back and tell you how I got to that Tennessee/Alabama game. I had moved to Alabama in 1980 after finishing a fellowship in a large medical center in another state. I grew up in a big metropolitan town and thought I had the world by the tail when I finished my fellowship. I had trained at a nationally recognized medical center. My ego was sky-

high. I practiced in Corpus Christi, Texas for a time, but because I wasn't the chief in charge of everything, I elected not to stay. I finally came to Alabama when a large opportunity to run a specialty unit was opened. I also worked in the teaching in the hospital and because they had never had a sub-specialist I really thought I was something. My drinking escalated when I came to this small town because I thought I was on top of the world and had nothing left to fill the void that had obviously crept up in me. As my drinking escalated my escapades became larger than life. I don't really think this town know what to do with me. I was kicked out of our local country club twice, had various run-ins with so many people at social functions, always explaining my way out of it, and saying that the other side was always at fault, and they just couldn't see things my way. I was really good at blaming other people for my personal problems I had created.

"Approximately a year and a half to two years before the final episode, my drinking, my tolerance for alcohol began to diminish. I began to take an occasional Xanax or Valium in order to get the same effect and not have as many drinks. My practice had grown somewhat in spite of me. I also was working out, calling football and basketball games, running, and trying to keep in shape. I was trying so much to stay out in front and have everyone's approval that I almost killed myself.

"You might ask yourself, 'Well why does a prosperous sub-specialist have to go into the emergency room business?' Money was always tight. We took wild trips. My wife and I went to Las Vegas on a whim, we went to our beach condos, and we were always in debt and always behind. Approximately a year and a half or a year before my intervention, a close personal friend of mine who worked in the emergency room was very sick and our emergency room could not get coverage.

"Again, here was my ego and control coming out. I said, 'Well, I'll help out,' and I said I was doing this to help out, but really I wanted the money, and I was fairly good at it. They asked me to work more and more and as they did the constraints on my free time to get out and drink became less and less. On occasion I would rush home just about a quarter to six when my time for the emergency room went out and grab a couple of belts, saying that I was on the car phone. Numerous nights I took call at home when I was either passed out or intoxicated. I frequently fell asleep in my chair eating supper at 8:30 or 9:00, only to wake up at 11:30, food all over my chin and chest, not knowing where I was, then crawling back in the bed sheepishly with my wife who had gone to sleep.

"These types of escapades and this type of life continued for the last year up until my intervention. Despite myself, I succeeded in some things. I was president of our medical staff for a couple of years, joined numerous societies, but always felt very empty and like there was always something missing. Nothing was ever good enough, lasted long enough, or sweet enough. There was always something on the other side. I suppose I could give you a lot more stories, a lot more escapades, but this is told not to hurt other people, and to not bring other people's names into it.

"I must say that at the intervention I was very emotional, was scared that my practice and my medical career would be taken away from me. I wasn't concerned for my wife and family, who I learned later were about to leave, or for friends who had left me. I was only concerned about my ego and the fact that, if I went away to treatment and I was branded an alcoholic, everything that I had worked for – that feeling of being in the limelight, of being accepted – would be washed away. I'll never forget the day that we had to show up in the hospital administrator's office on October 26th and how emotional, even teary, that session was. I left that Friday for an evaluation knowing in my heart that everyone would probably find out about me, telling my wife not to say anything, telling any friends if they called not to say anything. I wanted someone to tell me I was O.K.

"After the fourth day of evaluation I knew in my heart, after listening to other physicians tell their stories in group therapy, that I indeed was an alcoholic. However, I didn't really understand what an alcoholic was. I felt that it was only that I was drinking entirely too much. I came home, straightened some personal affairs, told my nurses and my secretary in a very emotional meeting that I had to go away for treatment. They seemed to handle it better than I did. I went back to treatment for thirty-two days and was finally released home, oddly enough on the Alabama/Auburn football day. Needless to say, I didn't go close to the stadium.

"The first six months were very rough at home. My wife felt that since I had been treated I should be like a recovered patient who had been successfully treated and be up and ready to go now. It wasn't that way. I was home at the Christmas season, which I loved, but I was a 'high bottom' drunk. I loved the crystal glasses, champagne, mirrors, tuxedos, and the women in long dresses. But none of this was for me because I couldn't drink now. I knew that I had to learn to live happily without the need for a drink. I must be quite frank when I say this now, two and a half years out, that I have developed honest relationships with people who I thought I had injured beyond repair. I feel honest respect from my friends, peers, and the people, nurses, and techs who work under me. I feel better about myself. Banks who I felt never would give me a second chance have opened their arms up. I have redone my house, my notes are on time, my debts are at least half paid off now, and my taxes are being paid about 80% up front by April 15th. My wife and I are active in the

program of recovery. She is in Alanon, and I can tell each day as we talk about God and what He has done in our lives, that even she is becoming more sold on this program of recovery. I now have a son who's in recovery, and I have two other children who I know feel better about me since I feel better about myself.

"You know, they told me at the treatment center that it would get better. Whatever 'it' was, that I would go back to, 'it' would get better if I would give up drinking and enter into a program of recovery. Today I am convinced that they are right. There is happiness out here and the happiness is much more full and much more lasting. I haven't found quite the gay, exotic, risky type of happiness that I had before, and maybe I won't have that again, but I can tell you that the peace and contentment that is found in good friendships and a job well done is infinitely better now. I can sleep at night. I am not worried and anxious all the time because I know in my heart I'm doing the right thing, and my life seems to be pointed in a right direction.

"It has taken a hospital administrator, the help of the Physicians Recovery Network, and the people at the treatment center. Most importantly, my family, the people who were very close to me, have been so much a part of my recovery because they have loved me and believed in me if I would believe in myself and do the right thing. There is life and there is good life and good happiness once you get rid of the bonds of alcohol. If you enter and stay with a 12-Step program you will find peace and more happiness.

"I have found more peace and happiness than I had heretofore ever know, and I will tell you that I am happier today than I was a year ago, and happier then than I was six months after I was out of treatment. Most importantly, I like me without alcohol and I feel others do too!"

The Physicians Recovery Network (PRN) is a confidential MASA program developed to promote early identification in physicians who are becoming impaired through chemical dependency, psychiatric or emotional illness. Physicians have difficulty in asking for help. PRN makes the process of helping easier by calling 1-800-239-6272, (205) 263-6441, or (205) 261-2044.

What Health-System Reform Means for Texas

By Mark Richardson, Associate Editor
In Texas Medicine

Texans will tell you, usually with some measure of pride, the things are different here. We wear boots and jeans much of the time, polished and pressed for formal occasions. There are mountains in the west, pine forests in the east, coastal plains in the south, and urban sprawl in the north. We eat salsa on just about everything. There are mega-cities with booming populations and rural counties that are larger than some states. Rich and poor alike prefer pickup trucks over luxury cars. And we are more than 100 ethnicities and cultures who say "Howdy, y'all!" in languages ranging from Armenian to Tex-Mex. Amid the furor of the current debate over health-system reform, it is clear that a health-care delivery system designed for middle America will likely be difficult to implement in a state as large, diverse, and complex as Texas.

Texas is a land of health-care extremes.

Within its borders are some of the world's largest and most-advanced medical centers, thousands of physicians recognized as top experts in their specialties, and a $1 billion infrastructure of academic centers and private foundations doing world-class biomedical research.

But Texas also has some 3 million people without health insurance (10% of the national total), 23 countries without a primary care physician (18 with no physician whatsoever), and an 868-mile border with Mexico along which more than 180,000 people live in *colonias* with poor drinking water, no sewage facilities, and the diseases that come with Third World poverty.

From a physician's economic outlook, Texas has an extremely high rate of liability lawsuits and a much larger than average Medicaid population, with 23.8% of rural residents living below the poverty line.

To say that Texas presents a unique challenge to the health-system reform process may seriously understate the case. Perhaps no other population in the United States has more at stake in health-system reform than Texans and their physicians.

DeAnn Friedholm, Texas Medicaid director and a member of President Clinton's Health System Reform Task Force, says that from her perspective, no other state faces the problems in delivering health care that Texas does.

"It is fair to say that we in Texas will have a disproportionate share of obstacles to overcome in implementing a new health-care delivery system," she said. "We will have enormous problems to deal with once a plan is adopted and passed along to us to implement."

The challenge for Texas, according to Texas Medical Association President Robert M. Tenery Jr, MD, is to address the state's critical healthcare needs without lowering the standards set by our world-class physicians and institutions.

"We support any move toward universal coverage for all Americans without sacrificing the quality of health care available to the vast majority," he said. "However, (we) caution our patients, the Congress, and the administration to consider carefully the consequences their decisions will have on everyone in our country.

"The reforms must take into consideration the diversity of our great country and our state," he added. "One size will not fit all."

Texas physicians have reacted to the Clinton reform plan with mixed feelings, applauding its call for universal coverage and portability, reduction of paperwork hassles, and emphasis on prevention, while showing considerably less enthusiasm for its heavy reliance on managed care, potential interference with the physician-patient relationship, and lack of adequate measures to address liability issues.

Other major reform issues of concern to Texas physicians are the development of guidelines to measure the quality of care, provisions to address the state's overwhelming public health concerns, the effect mandated insurance coverage might have on Texas' many small business, and the effect reform will have on medical education and research.

Many Texas physicians have reacted to Clinton's proposals with apprehension and, in some cases, outright anger, feeling that some aspects of the president's plan will drive a wedge between them and their patients and allow the quality of health care to deteriorate.

Miles and miles of Texas

Texans are known to exaggerate when it comes to describing the dimensions of various items in their state.

But when it comes to getting from one point to the other, it's hard to overstate just how isolated some parts of rural Texas can be. And Texas physicians are extremely concerned that the Clinton plan's heavy emphasis on managed competition will leave rural health care in a quandary.

It is not unusual, for example, for a West Texas physician to provide the only medical care within a 150-mile radius. There are several instances where a single hospital serves as many as three rural counties.

Who are these physicians and hospitals going to compete with for health-care contracts? And how does a health plan gain an economy of scale with such a small population base?

"Unfortunately, President Clinton's plan does not do much for rural health care in the short term," said Ms. Friedholm. "It puts the states in the position of having to provide all residents, rural and urban, a choice of health-care plans and an adequate level of services. It's going to be a real challenge to make that happen in a state as big and diverse as this."

But she was quick to add that the plan does have several long-term benefits for rural Texans.

"The plan includes many incentives for schools to produce more physicians in traditional primary care specialities," she said, nothing that it will take several years to reach the desired goal of 55% of Texas physicians practiced in non-primary care specialities.

Currently, fewer than 10% of the state's physicians practice in rural counties, while almost 20% of the state's population lives there. The physician-patient ratio in rural Texas is 1,395 people for every physician; there are 684 urban dwellers to each physician.

Consequently, 1 our of every 2 rural Texas counties is designated by the Texas Department of Health as a primary care health professional shortage area. And 9 out of every 10 rural counties contain federal census tracts designated as medically underserved areas.

Further complicating the rural health picture is the fact that poverty and unemployment are consistently higher in rural areas of the state. According to TMA's healthcare financing department, 1 in 6 people in rural Texas has no health insurance. In recent years, the poverty rate among rural Texans has run between 20% and 25%, considerably higher than the United States population as a whole.

The invisible border

Mention the Texas-Mexico border and two trains of thought usually collide.

For many, a trip to the border conjures up images of shopping expeditions, flowing tequila, and endless fiestas. But for many who live along the border, it's a nightmare filled with cholera outbreaks, the absence of clean water, and inadequate health care.

"There are definitely misconceptions, along with a lack of knowledge about life on the border," said Antonio Falcon, MD, of Rio Grande City. "Attention has to be paid to border health because it affects the whole country."

As the reform debate gears up, there are already fears that border health issues will once again be ignored. And those living in a fantasy world will continue to believe healthcare problems such as tuberculosis, cholera, and hepatitis will disappear if nothing is said or done.

Under the current proposal, unemployed illegal aliens will not be eligible for coverage under the plan. However, individuals crossing the border in search of medical care at hospitals or public health clinics will still be treated. The tab will be picked up either by Medicaid or local funds, or go uncollected.

"The current avenues of medical services available, such as migrant and community health centers, will still exist under the plan," said Carrie Luttbeg, legislative assistant to US Rep Ron Coleman of El Paso. Representative Coleman is cosponsor of a bill introduced in Congress last year creating a Binational Border Health Commission. If given congressional approval, the commission would be develop public health strategies to reduce rates of communicable disease and environmental illness in the border region. TMA and AMA are strong advocates of the bill.

It's no secret Texas counties along the border rank high on poverty lists; physicians and hospitals are scarce and biblical diseases are making a comeback. The 15-county, 868-mile-long border region is one of the poorest areas in the nation, with an average per capita income of $7,700. The border population between El Paso and Brownsville is 1.5 million, with another 2.1 million in Mexico.

The lure of home ownership has led to an increase in the number of *colonias* – rural, unregulated subdivisions that offer inexpensive lots for sale. These areas often lack potable water, sewage systems, drainage, paved streets, or other basic necessities of urban life. A recent study issued by the governor's office reports 7 of the 15 counties on the border have no hospitals; all are either totally or partially designated as medically underserved, and all but one are designated as health professional shortage areas.

Physicians, hospital administrators, congressmen, and taxpayers are all pondering how much money will be available and who will pay to improve current environmental and health standards on the border. The governor's report claims $1.9 billion will be needed over the next 8 years to improve basic health and human services.

Local and state funds now are shouldering a burden that some consider a federal government responsibility. "We don't think it's fair that a large percentage of the money being used for healthcare care is coming from local and state sources," said Ms Luttbeg.

Managing the medical marketplace

Our reputation as a state filled with rugged individualists is borne out in the medical marketplace, where, in the face of a 20-year national trend toward group practice and managed care, the vast majority of Texas physicians are still in solo practice on a fee-for-service basis.

In fact, according to AMA statistics, more than 75% of all Texas physicians in 1991 were solo practitioners. In that same year, managed care plans had penetrated only 11.5% of the market in Texas.

Thus, a health-system reform package that encourages large health alliances and vertically integrated delivery systems, and that – despite the inclusion of a higher cost indemnity option – banks heavily on HMOs and PPOs to deliver care, is likely to cause a great deal of disruption for both physicians and their patients.

According to Louis Goodman, PhD, TMA's director of medical economics, Texas may have to compress the kind of market changes that occurred in other states across several decades into just 2 or 3 years.

"California has 34% managed care, New York has about 21%, and it averages about 17% for the rest of the country," Dr. Goodman said. "But California and New York took about 20 years to put those systems in place and adjust to the changes. Texas is not going to have that amount of time. It may be 'Wham! It's here. Deal with it.'"

That is likely to cause a major disruption in physician-patient relationships, established referral patterns, and patients' habits in seeking health care, he says.

"Many Texans, for the first time, may not be able to see the doctor who has looked after several generations of their family," he said. "The competitive inequities in t he current market are seeing qualified doctors being kicked out of managed care plans – they call it 'deselection' – and forcing their patients to go elsewhere. There are going to be a lot of people unhappy with that situation."

Texas also has a higher percentage of uninsured than the nation as a whole. While approximately 15% of the US population lacks health coverage, close to 19% of Texans are uninsured. In fact, uninsured Texans account for about 10% of the nationwide total of uninsured.

And while other states can rely on large industrial companies for the bulk of employment, the Texas economy depends more heavily on small businesses as employers, many of whom currently do not provide insurance for their employees.

"The imposition of an employer mandate to provide coverage for these workers would be a major financial burden on small businesses," Dr. Goodman said. "Most likely, it would mean a loss of jobs in the state."

Texas also carries a crushing burden of Medicaid, Medicare, and charity care patients, particularly in the rural areas. According to Medicaid figures, at least 11% of the rural population is enrolled in the program, putting a higher burden on rural physicians who have no choice but to accept the lower reimbursement rates Medicaid pays.

There is, however, some relief planned for Medicaid physicians, according to Ms Friedholm.

"Under the Clinton plan, Medicaid patients would become essentially invisible to the providing services."

Upping the ante

In looking at just how President Clinton's Health Security Act might affect Texas, the problem for health-care planners becomes how to avoid burning down the house in order to save it.

Texas' current system of healthcare delivery has provided many of the state's residents with high-quality health care. But the Texas health-care system faces an array of challenging problems, such as an underserved and impoverished rural population, a massive influx of immigration and poverty, high rates of infectious diseases, and an impending disruption of the medical marketplace.

Several key questions must be addressed to make health-system reform work for Texas:

- Can a plan be devised that will bring low-cost, high-quality health care to all areas of the state, urban and rural?
- Can a short-term strategy be formulated to increase the supply of primary care physicians?
- Will the reform plan to be able to address the special health needs of the state's border populations?
- Can Texas maintain its centers of medical excellence at their current levels while extending universal health care to its citizens?
- Will the final reform package give Texas and other states the flexibility to tailor the health-care delivery system to its needs?

Crafting a health-system reform plan that meets the state's needs will be arduous task for organized medicine. But given what is at stake for Texas physicians and their patients, organized medicine has no job before it of greater importance.

Associate editors Laura J. Albrecht and Ken Ortolon assisted in the preparation of this article.



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What computers can do for you

*Bob Carlson**
In Indiana Medicine

If you think the health care system is changing fast now, you ain't seen nothin' yet. Before you stick more pins in your Bill and Hillary dolls, hold on. The truth is, it probably all would have happened anyway. And one of the biggest reasons is computers.

If you're like most physicians, your practice management functions have probably been automated since sometime in the '80s. Things like billing, accounts receivable, insurance processing and appointment scheduling - front office stuff. That was the '80s. It's 1994, and now it's your turn.

Exam room, late 1994

You greet your patient, close the exam room door and sit down. With a plastic stylus in hand, you touch the screen of your portable laptop computer to instantly display the patient's chart. As you talk with the patient, you complete the medical record for this encounter, again, simply by touching the plastic stylus to the computer screen. Subjective, objective, assessment, plan. You touch the screen, and a laser printer in the corner of the exam room quietly prints out a prescription and four pages of patient educational material. You ask about the family.

The patient's electronic chart now includes all the data you entered moments ago on your laptop. As the patient leaves your office, another laser printer automatically generates a hard copy that will be filed with the old paper chart in the file room at the end of the day. You touch the screen with the stylus. Two minutes behind schedule, you pick up your laptop and head down the hall to see your next patient.

A laptop in every lap?

This scenario is not science fiction. It's based on cutting edge technology and will be a reality in at least one practice right here in Indiana by the end of the year. If you look past the bells and whistles, it's obviously a great way to save time, improve care, cut down on paperwork and boost efficiency.

Those are also the reasons you invested in a computer system for the front office, remember? Computers revolutionized the business side of practicing medicine, and now almost no physician would be without them.

And that's exactly the point. Computers are driving change in health care, perhaps more than you-know-who in Washington, D.C. Without computers, there would be no HMOs, no utilization review, no smart cards, no electronic charts and no information highway.

So if you can't see yourself with a laptop in your lap, you may not be practicing medicine in five years.

Superdocs in Evansville

Greg Hindahl, M.D., and Kim Volz, M.D., can't wait for their laptops. "A monitor in every exam room gets expensive. That's why we went to the laptop system. You can just carry it from room to room," explains Dr. Hindahl.

Actually, they already use laptop computers in their Evansville family practice. It's *touchscreen* laptops they're waiting for so they can have both the portability of laptops and the speed of the SuperDOC program they helped develop for family practice use. The SuperDOC program is fast because it allows the physiogy to touch the screen with a stylus and select words when doing dictation. No transcribing necessary.

"Ideally, you finish the note and it gets printed as the patient is leaving. If they call back an hour later, you've already got a typed note. For acute illnesses in family practice, especially if you're seeing a lot of sick kids, it's nice to have immediate access to those notes when you get a call at night," says Dr. Volz. Immediate access? With portable laptops, of course, which go wherever Drs. Hindahl and Volz go.

For Dr. Hindahl, the biggest advantage of using laptops comes into play in a group practice situation. "When you're on call for the other person, unless you want to go to the office every time a patient calls, you don't have a very good idea of that patient's medical problems. With a laptop, you have all the vital information you need to give that patient a good answer while you're talking to them on the phone, no matter where you are."

While waiting for their touch screen laptops, they still dictate their notes the old-fashioned way, have them transcribed and entered in the office computer network. At the end of the day, it takes about 30 seconds to update their laptops with that day's notes from the network.

They use another program called SOAP, which they describe as basically an electronic chart to keep track of patient information. It also checks for drug interactions, automatically, and has a "Chart Card" option that allows a patient's records to be transferred onto a plastic credit card device or onto a regular floppy disk. If the patient needs to see another doctor, the patient's entire medical record is instantly available to the new doctor.

Drs. Hindahl and Volz admit to being excited about using computers in their work. Their front office is

*The author is a health care communications consultant in Indianapolis.

also computerized, but as Dr. Volz explains, "The front office is really not handled by us. We just know it's there and does its job. As physicians, what we're actually working with is the clinical part."

Try it, you'll like it

There's good reason to concentrate on the clinical side, maintains Ben Park, M.D., a family physician in Lebanon, Ind., and president of Advanced Medical Information Systems in Indianapolis.

"If you have a clerk in the front office that's making $20,000 a year and you improve that person's productivity by 10%, what's your gain? Now take a physician who's making $100,000 a year and improve his or her productivity 10%. It's clear where you ought to be spending your money."

As everyone becomes more cost-conscious about health care, he also sees increasing pressure on physicians to be as efficient as possible and to provide more information about how they take care of their patients.

Dr. Park, who went to graduate school in computer science after completing medical school, founded Advanced Medical Information Systems in 1986. The firm specializes in turnkey office automation systems for the physician's office. "Our focus is on the medical side," says Dr. Park, "although we do the other things, too. Billing, scheduling and sending electronic claims are kind of a given in today's market."

His advice, from one doctor to another?

"Try it, you'll like it. And your nurse'll love it. And if your nurse is happy, you're happy."

He cautions, though, that a computerized medical records system is entirely different from a practice management system. "A practice manager might make the decision about what kind of billing system to get, but not what kind of medical records system. This is a physician decision. It's highly personal."

Managed care and the highway

In a managed care environment, the primary care physician is the gatekeeper for all health care in the patient's life. Equipped with a computerized clinical information system, the physician is responsible for managing the patient's care, whether that care is provided in the office, by a specialist to whom the patient is referred, at a lab or by a pharmacy. To do that, the physician must be able to access data across the continuum of the patient's care.

Here's another scenario. A patient visits his doctor on the south side of town, is treated and released. An hour later, he is involved in a traffic accident on the north side of town. He is rushed to a hospital emergency department, where his number is entered into the computer. His complete medical record appears on the screen, including his physician's office visit notes, and a potentially harmful drug interaction is avoided.

How did the notes about the office visit get from the physician's office to the hospital's emergency department computer? Via the information highway, of course, which links every provider with every other provider. End of scenario.

According to Stephen Furry, partner in health care information systems consulting with Ernst & Young in Indianapolis, three new components are necessary to make this scenario possible.

First, a common patient identifier.

Furry explains. "When I go to a physician office now, I'm assigned a number. When I go to a hospital, I'm assigned another number. When I go to a lab, I'm assigned another number. When I go to an HMO, I'm assigned another number. If my doctor is going to manage my care across these entities, he or she has got to have a way to identify Steve Furry in the entire process."

Second, a *clinical data repository*. This is the patient's automated medical record, which is made up of information from a number of different care-giving entities, including the physician.

Third, the *information highway*, which electronically links the caregiving entities to each other and to the clinical data repository.

These three components need to be community-wide, says Furry. He compares the entire system to bank automatic teller machine (ATM) networks. "The only difference between an ATM network and a medical network is the amount of data being moved around. When you start moving an x-ray from point A to point B, you're talking about a huge amount of data. As soon as technology catches up, you're going to have clinical networks like you see ATM networks."

How soon will technology catch up?

"We're probably five to 10 years away from nationwide coverage," says Furry. "Before then, you're going to see pockets of local clinical networks."

Michiana Health Information Network

Northern Indiana may be one of the first clinical network pockets in the country. Alan Snell, M.D., admits he's not a technical wizard when it comes to computers. But he has a vision.

"I'm on the medical staff of two hospitals. I am also a customer of the South Bend Medical Foundation, which we use as our lab in my own practice. Then there are the radiology groups associated with each of the hospitals. I can envision our own computer system in the office linked to these other entities so that my staff, my two associate physicians and I can call up data from any of these entities," says Dr. Snell. About 18 months ago, he assembled the Michiana Health Information Network, a task force representing different health care institutions in the South Bend/Elkhart area, all of whom were already computerized. Consultants and computer systems vendors, communications companies like Ameritech, and people involved in similar networks elsewhere in the country were invited. Site visits were conducted.

"A lot of it was just fact-finding and getting educated," says Dr. Snell, "trying to decide what obstacles we

ASIM endorses patienl records soflware

The American Society of Internal Medicine (ASIM) recently gave its endorsement to a patient records and office management software package developed by MedicaLogic, Inc., of Beaverton, Ore. The software was designed by internist Mark Leavitt, M.D.

ASIM officials said the software stood out from the more than 300 proposals submitted because it is tailored to the practice needs and work habits of internists. The patient records software, ClinicaLogic, allows physicians to access patient information away from the office. A software option called PharmacoLogic lets physicians find out drug prices and ensure patients get the most effective drugs for their illnesses. Currently less than 5% of physicians use electronic clinical records. ASIM hopes its endorsement will encourage physicians to move away from paper clinical records and incorporate computers into their day-to-day practices. For more information on MedicaLogic, call Sue Reber or Mark Leavitt, M.D., (503) 645-6442.❑

would have to overcome."

One of the obstacles is a clash of cultures in the health care community: the hospital culture versus the physician culture, for example. There is also an unwillingness to share information, one hospital with another, one physician with another. "There's still some feeling of proprietary information," says Dr. Snell.

As a physician, Snell is enthusiastic about another potential benefit of a health care information network, i.e., using the community health care database to assess community health status. How much information is going to be needed? Who will have access? Dr. Snell believes the Michiana Health Information Network's common goal of community health and a growing spirit of collaboration will help to find solutions to these and other questions.

"As we are successful in collaborating on information sharing, we can start asking ourselves whether we as a community can share our health care resources in other areas such as facilities, bed space, centers of excellence, transportation systems, instead of duplicating them. It's going to be too difficult, too costly, too timeconsuming to try to be everything to everybody. This may be a good way for us to build those trust relationships. The chemistry is right."

MedNet at Methodist Hospital

About 140 miles south, in Indianapolis, Methodist Hospital is building its own piece of the electronic highway. It's called Indiana MedNet, and if you're on the medical staff at Methodist, or have a close referral relationship, it won't cost you a dime to have your workstation connected to the network.

More than 200 physicians are on Indiana MedNet so far. That's right on target, according to Barbara Stayton, Methodist's director of physician services. The network's first day of operation was Sept. 20,1993. She projects 300 subscribers by the end of 1994.

Physicians on MedNet are electronically linked to different components of Methodist Hospital, its subsidiaries and off-campus sites. Instead of spending time on the phone or waiting for the mail, subscribing physicians get their reports from the hospital electronically on their office computer. Some access their office computer from home via modem.

Stayton explains that because of the hospital's size and the volume of paperwork that goes to physicians, the flow of paper is sometimes not as timely as physicians would like. "If we can send it electronically, it's better for patient care, and it's certainly easier for physicians and their office staff."

Indiana MedNet subscribers continue to receive their regular Methodist mail for the first 30 days. Then they're asked if they're ready to have the paper flow turned off. "We want them to have a comfort level before we do that," says Stayton.

Next to go on-line are the hospital's medical records department, transplant services, operating room services, radiation therapy and Indiana Home Health, a subsidiary of Methodist Hospital. Eventually, Indiana MedNet will link physicians, pharmacies, managed care companies and other hospitals throughout the state.

"Traditionally, hospital departments have not interacted one-on-one with physicians. This is a different mind-set. We're not doing this to meet our needs. We're doing this to meet the needs of the physicians," says Stayton.

Caveat emptor

"Some physicians are on their second or third practice management system and are looking for a third or fourth," says John Moeller, account representative with Horine & Associates in Indianapolis. Horine & Associates specializes in physician software.

Moeller suggests that the reasons for replacing systems this frequently point to faulty selection criteria. The computer system is not expandable to keep pace with a growing practice. The system has not performed as promised, or system support may have been inadequate.

Medic Computer Systems in Indianapolis also markets medical data processing systems to physicians. "I think some people look at the initial cost only and ignore the long-term cost. That could mean they have to buy a whole new system if they want to go from two terminals to three terminals, " says Gary Havercamp, Medic Computer Systems regional sales manager.

When upgrading an existing system or installing new capabilities, such as a computerized clinical records system, Moeller and Havercamp caution that a variety of factors other than price should be considered. In their promotional literature, medical computer systems vendors often include a chart entitled "Buying Criteria" to illustrate this point.

Criteria used by "First System" buyers, in order of importance, are price, ease of implementation, ease of use, software fit, function, equipment, growth, supl port, documentation and vendor. In contrast, more enlightened "Second System" buyer criteria are support (56%), vendor, equipment, growth, software fit, documentation, function, ease of implementation, ease of use and price.

"You're buying the business partnership as well as the computer," says Furry.

Furry emphasizes that of the three components in a physician's medical information system, the financial (billing and general accounting), the administrative (scheduling, registration, word processing) and the clinical (from office visit notes to complete patient medical record), the clinical component is the least developed.

"The clinical information products that are out there aren't very mature. But by the same token, there is very, very high value and high benefit associated with these systems if you put them in right." Havercamp of Medic Computer Systems illustrates the potential benefits of clinical information systems with an analogy. "It's kind of like buying a car in February. You may not think you need air conditioning, but you're glad you've got it in July."

With new technology such as voice recognition software making headlines, Moeller of Horine & Associates cautions physicians to "make sure you're buying steak and not sizzle. There are a lot of hot articles in all the physician magazines about all this neat, fun stuff. Well, it is neat and fun, but some of it is not really ready for application in a live environment."

How to get there from here

"Several years ago, I was at the American Academy of Family Practice annual meeting and encountered a couple of vendors who had electronic chart programs," recalls Dr. Volz when asked how he and his partner, Dr. Hindahl, became interested in using computers in their clinical work.

Dr. Hindahl says the academy has a session about computers at every annual meeting so people can learn about what's abailalbe, what works and what doesn't. "When you work with hardward and software both, it's just a continual weeding out process."

Their advice? "First, decide what you want the system to do. Then you have to look at each software application and see if it does what you want. Definitely try it. Don't commit to buying a program and find out two weeks later that the way it works is totally alien to you and that you don't like it."

Dr. Park agrees. "Decide if you want to make any changes in the way you practice now, and then look for a system that can accommodate the style of practice you want." He also encourages physicians to attend trade shows like the one sponsored annually by the Society for Computer Applications and Medical Information in Washington, D.C.

Today, the practice management component of Ireland Road Family Physicians in South Bend is automated. Within five years, Dr. Snell thinks the practice may be completely paperless. "Our goal will be to use hand-held, note-pad type computers that you can carry from exam room to exam room or even to the hospital. We also want to get into interactive patient education software.

"Sometimes the easiest way for physicians to get comfortable with technology is to just do the practice management part. See where the efficiencies are, where the problems are and learn how to deal with them. Then they'll be more comfortable with computerized medical records and information sharing," says Dr. Snell.

"If you have someone on staff who is knowledgeable, that's really the best choice," advises Moeller. "If you don't have anybody in-house, get a hired gun. A lot groups use consultants. Step two, with the resource, develop your true needs. Really figure out what you want before you go out into the marketplace and get barraged by all the different products. A lot of groups start with vendor demonstrations before they know what they want. They buy it, and it doesn't meet their needs because they really didn't develop their needs.

"Another tremendous resource for physicians is the hospital. Go to the physician relations person and say, 'I'm looking for a system. Do you have anybody who can help me with that?'"

Havercamp recommends three steps. "First, see a demonstration by the vendor to get an idea of the capabilities of that system. Second, go on a site visit to see the system in action at a real practice. You might want to make two or three of those visits, with or without the salesperson. Third, maybe a more detailed demonstration with the vendor's trainer along to answer the doctor's and staff's detailed questions."

Furry says medical societies and physician associations are putting on more trade shows, "but you'll be faced with salesmen trying to sell you a system. Unfortunately, those shows don't do a good job of training a physician what to look for, what differentiates a system, what makes a good system, what makes a bad system."

To analyze needs, to find out what's in the marketplace, to answer questions about system implementation, training, support, maintenance, enhancement and expandability, physicians need a professional, says Furry. Not surprisingly, he recommends himself. "I'm an adviser. I don't sell it." "I would also turn to medical schools, because they don't sell it, either. Their business is research, data collection, clinical profiling. They're in the medical information business, so they've had an opportunity to try these systems. Doctors can talk to their peers.

It's a very clinically oriented environment. Dr. Clem McDonald at Regenstrief has been collecting patient data for 10 years on a system that he developed." (Dr. McDonald is co-director of Regenstrief Institute for Health Care at the Indiana University Medical Center in Indianapolis.) Finally, there's the free, no-obligation initial consultation. "Sometimes what physicians are looking for is something we can provide over breakfast or lunch. Often that's all they really need. Hopefully we can share enough of our experience that they'll have a better understanding of what's involved."



Mrs. William Hall
A-MASA, President

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Auxiliaries across our nation promote health education and services, which last year included...

300 initiatives in 34 states to make people aware of family violence and to provide support to its victims;

500 programs for older Americans, including day care, educational forums, equipment loans, hospice care, meals and transportation services, and medication record programs;

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1,300 community education and service programs on such topics as AIDS, CPR, drunk driving, nutrition, organ donation, parenting, spouse abuse, and substance abuse;

200 medical family programs, including educational seminars and support groups on impairment, marriage, and professional liability;

200 safety programs to promote the use of child restraints and seatbelts, as well as home, street and water safety;

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A-MASA is one of the oldest and largest volunteer organizations in Alabama with a diverse membership of more than two thousand physicians spouses.

We are community oriented. Our hands-on work is done at the county level, where projects and services fill local needs and priorities. We listen to our members and help them to make a difference. The State Auxiliary provides materials and resources to help county groups he more effective. And our national connection with the AMA Alliance makes us a powerful volunteer force nationwide with programs in all 50 states.

Our Membership Chairman is Usha Bhuta from Montgomery, she provides the following article.

All You Wanted To Know About A-MASA Membership

Myth. I am a male spouse and don't want to feel uncomfortable by joining a doctor's wives group.
Fact. We are not just doctor's wives anymore. There

are many male spouses who ar emembers of the Auxiliary and contribute their expertise to this worthwhile organization.

Myth. The Medical Auxiliary is for the birds, I cannot stand around sipping coffee and wasting my time.

Fact. Go past the coffee pot and you will find a group of auxilians who have made a great impact on health care in their communities.

Myth. I am a working spouse and have no time for the Auxiliary.

Fact. If you are unable to participate, remember, there is strength in numbers. We still need your support. Your dues can help support health projects in your community, across the state and the nation.

Myth. I have done enough for the Auxiliary in my younger age and now I don't think that I will benefit from the membership.

Fact. You have many friends in all those years and it will be to your advantage to keep in touch with them. In come counties there are groups called "KIT" which means Keep In Touch. Members who are fifty and over can join this group and enjoy the gatherings.

Myth. I do not have an organized medical auxiliary in my county so I guess I am out of luck.

Fact. You can organize a county if you have even three interested members. The State Auxiliary will be glad to send a representative to help you in organizing your county.

Myth. My spouse is not a member of AMA so I don't think I can quality for national membership.

Fact. If you spouse is not a member of AMA but is qualified to become one, you can join the National Organization as an Associate Member.

Myth. I am a resident physician spouse so I do not qualify to join.

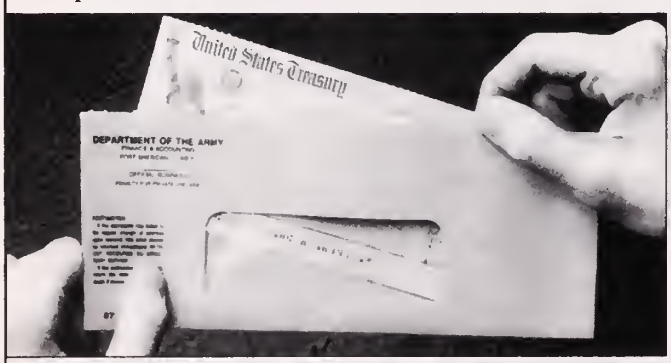
Fact. A resident physician spouse may choose to be a regular or associate member if they meet the criteria.

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First Vice President
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Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

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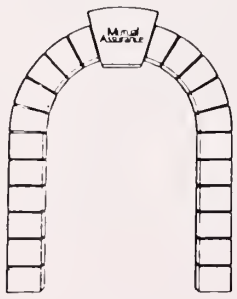
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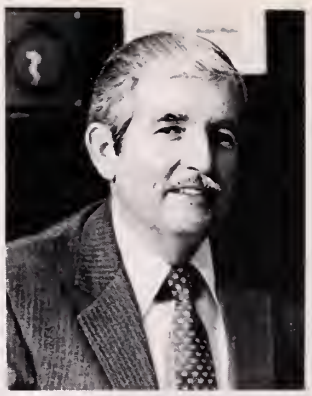
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S. Lon Conner
Executive Director, MASA

Meanwhile, Back on Main Street USA

In the middle of complicated and protracted debate, such as the one over health care reform, we tend to develop a kind of traveler's myopia, our sightseer's eyes fixed on roadside details and minutiae as they flash by.

In such a state, we may ignore the distant surrounding countryside and forget the long road behind us. All the big cities and hamlets we passed through long before have now become telescoped and blurred in memory, eclipsed by the ever-changing current scene.

If it is a very long trip, as the health care reform controversy has been, we may even have some difficulty remembering our original purpose for the journey.

Was the present health care debate really prompted by Harris Wofford's exploitation of "the health care crisis" in his stunning upset of Dick Thornburgh in the Pennsylvania Senate race in the late fall of 1991?

That was an alarming event, but it wasn't the earliest reason for this journey.

After all, AMA had already declared an emergency in health care costs and *JAMA* had already said that total health care expenditures were doubling every six years and that the system was threatened with "meltdown."

Surely, then, it was the oft-repeated lamentation that 37 million Americans were uninsured? Not really. That provided considerable political impetus, to be sure, but the groundswell for reform had begun even before that, according to Bob Blendon, M.D., of the Harvard School of Public Health.

Dr. Blendon is principal author of a study showing how patients with what they thought was comprehensive health insurance are facing ever-increasing out-of-pocket costs as employers and insurers shift larger portions of the health care bill to employees.

Personal outlays for medical care have risen steadily since the early 1980s, but the trend has accelerated in recent years, with 1994 estimates showing another leap. The survey results, published in *JAMA* in March by Blendon, et al, found one in five families reporting problems paying medical bills. The researchers were surprised to learn that nearly three-fourths of those families were insured. Dr. Blendon explained to *The New York Times* (May 12, p.1.):

"We believe that we're having a national health debate because of the reduction of benefits that people are experiencing. You're covered for less. You're paying more. And you're nervous about what is going to happen in the case of large medical bills...

"The problem is that many people's insurance is not as deep as they think, and their medical bills are not being paid for adequately by insurance.

"You don't have absolute security. The real message of our survey is uncertainty: you think your insurance is going to cover you and the answer is, maybe you're right."

Although certainly familiar to doctors, the habit of insurers refusing to pay amounts beyond what they adjudge to be reasonable comes as a profound, sometimes devastating, shock to millions of Americans lulled into a false sense of security by their memories of what used to be — the good old days when health care was essentially "free."

For example, most of the bitter conflict in negotiating labor contracts in recent years has been over this very issue — not wages, as such, but the increasing

employee share of premiums, escalating deductibles and co-insurance and other cost-shifting insurance contract provisions. Similarly, AARP has reported increasing balance-billing hardship by its members on Medicare.

A new AARP-funded study projects that out-of-pocket medical care costs for the average older American this year will be $2,803, or about 23% of their household income. (Earlier studies suggested that the elderly, in constant dollars, are paying about the same out-of-pocket for medical care as they were before Medicare. Of course, they are getting a much higher level of medical care, what with all the advances in the intervening years.)

But the cry of pain that has attracted the most political attention in this regard is coming from the working, middle class Americans already carrying a heavy premium load, either in direct costs are as salary offsets — wage levels suppressed by their employers' increasing health care burden. Organized workers in many instances have been able to negotiate health care packages with benefits considerably more lavish than unorganized labor forces, but they have done so, they contend, by trading off other emoluments, including wage increases.

The health care insurance anxiety is seen here too: most strikes in recent years have been precipitated by contract disputes over health care benefits rather than wages per se. It has been said that many union meetings across the country are now dominated by this one issue, almost to the total exclusion of other business.

Even though workers may be increasingly distressed over the restriction of benefits, they are fearful of losing what they have — either by their employers' actions or the consequences of being forced to change jobs.

While it has been argued over the years that individuals should pay a portion of their health care costs through deductibles, co-insurance and the circumscribing of benefits, it should be remembered that most economic surveys have shown salaried workers with far less discretionary income than, say, 20 years ago. This is exacerbated by rising deductibles and by medical cost inflation: 20% of the cost of a serious illness at 1994 hospital prices is a much higher tab than 20% of the cost of the same illness 20 years ago, or even 10. Therein lies the key to much of the public pressure for health care reform.

Among the conclusions in a report by the Henry J. Kaisar Family Foundation and the Commonwealth Fund was this:

"One of the key drivers of Americans' attitudes toward health care services and the system in general is out-of-pocket medical expenses. The level of dissatisfaction with services and with the system increases as out-of-pocket costs increase."

And here is the crux of the national distress. Americans realize they have the finest system in the world, but there is a rising fear of being priced out of access to it because of the heavier and heavier share they must pay. It is very likely this mood, more than the despair of the millions of people without insurance, that clobbered Mr. Thornburgh and is still out there as Congress intensifies its consideration of the many and varied approaches to reform.

Unless Dr. Blendon and others who have taken the public pulse are wildly amiss in their findings, the mood of anxious Americans was not permanently altered by Harry and Louise, or by other assurances that "you never had it so good." While elements in Congress would prefer that this issue go away, obviously it's not about to.

PRESIDENT'S PAGE



Garland I. Hall, M.D.
President, MASA

Life Jackets for Lemmings

The shark-filled sea around us, for as far as the eye can behold, is managed care — past, present or future. Scattered across the eerie landscape, right up to the edge of the cliff, alone or in groups, are mysterious figures in long black capes, deep cowls concealing their faces. They are said to be heavily armed.

We have learned that they are the drovers — a.k.a., claims people, bureaucrats, transplanted clerks, former carnival shills, minor-league hit men who never quite made it to the upper echelons of the mob, superannuated boxers, spavined old barroom bouncers and the like. What gives them that creepy aura of menace is their newly delegated power over us.

And their weaponry: powerful laptops and diabolical software with spurious, manipulated outcomes data going back to the time of Galen — all concealed next to their AK-47s. The function of these sinister heavies, of course, is to prevent any of us lemmings from breaking ranks as we are herded toward the precipice.

If that seems only a slightly hyperbolical version of your own nightmare fantasies, welcome. I cannot offer assurances that you will discover it's all just a bad dream. It may be virtual reality. But, just for a few moments of respite from thinking the unthinkable, let's zoom out from this bleak landscape and consider the larger world and what is happening in it. Perhaps from that perspective we can see more clearly whether or not us lemmings have a reasonable hope of surviving.

The microeconomics of medicine must always be fitted into the macroeconomics of the nation. Trying to make that fit has occasioned much of the agony already seen in Washington. If the health care industry generates (or "consumes" as reckless media boys like to say) one dollar out of seven in the U.S. economy, it follows that its destiny is tied to those other six dollars. What happens to those bucks happens to us as well. And all the old theories about the U.S. economy are collapsing. Here is *Fortune* magazine on that:

"We are, right now, in the very early stages of a new economy, one whose core is as fundamentally different from its predecessor as the automobile age was from the agricultural era. If you grasp this premise, it's much easier to understand a lot of what is going on around you, including why a seemingly unrelenting *tsunami* of change keeps washing over you"

The transforming agent, of course, is the microchip, which may seem old hat now but its power is now increasing exponentially, *Fortune* continues. A new greeting card that plays "Happy Birthday" when you open it has more computer processing power than existed in the entire world in 1950. You may have marveled some years ago at the IBM 360, which launched the mainframe era. Now your home videocamera has more processing power than it did. And remember reading about the original Cray supercomputer, which in its day (1976) was accessible to only the most elite physicists? Sega, the gamemaker, is about to begin selling a system, Saturn, with a higher performance processor than that legendary machine.

MIT's *Technology Review* recently noted that the eight consoles in the New York air traffic control center have, combined, only a fraction of the processing power in one secretary's word processing equipment just a block from the tower. This because of the long congressional and FAA delay in upgrading the national system, while commercial applications for offices have progressed rapidly. (Another illustration of the glaring difference between free enterprise and government?)

The chip is largely responsible for the fact that

almost 80% of all workers are now providing services, not goods as in the America of old. The percentage of the U.S. GDP contributed by manufacturing has been unchanged at 20% for 10 years, but productivity has increased spectacularly — principally because of decreasing numbers of workers and increasing numbers of chips. Because machines are much smarter than ever, employers can make do with fewer and less proficient people — a process some economists call "dumbing down."

Fortune again:

"... In the new economy almost every industry and every profession or trade is being pulled closer together by a common technological bond: the digitizing of its work product into the ones and zeros of computer language, in turn spawning revolutionary ways of executing that work. So, in the new economy, a gathering of thinkers from the worlds of say automaking, banking, medicine, retailing, art, film, publishing and aerospace could probably find common ground for professional conversation, perhaps even new ideas for tackling their own digital challenges."

In fact, this kind of cross-pollination has already begun. Film-maker George Lucas, of Industrial Light & Magic, profited by the *Star Wars* movie and the subsequent defense program so nicknamed, which gave him the Silicon Graphics workstation. That, in turn, begat the poly-alloy liquid-metal character called T-1000 in Terminator 2, which begat Ford's use of the same technology for molding auto parts.

After Jurassic Park, the auto industry began using the exact same software that had created dinosaurs to design the skin and interior features of prototype vehicles. Not incidentally, Silicon Graphics is already involved in medicine, having created 3-D "virtual" operating procedures.

Analysts are saying that where defense and aerospace were driving technology, it is now the entertainment industry. Silicon Graphics works for Ford, GM, BMW, Volvo, Boeing, for NASA, the CIA, Defense and the medical community, but its big bucks are coming form Lucas, Time Warner and Nintendo.

Needless to add, every nook & cranny in the house of medicine is now filled with chips doing, or trying to do, all manner of weird and wonderful things. And, also needless to add, managed care as we know and loathe it would be impossible without the computer's alleged ability to convert all human illness into binary code, thence into dollars, in much the same way that the yen can be converted into the peso.

So everything is changing at warp speed. You knew that. What will it mean in the larger context of health care delivery as we are dragged, kicking and screaming, into the 21st Century? Only a fool would pose as such a prophet.

There are, however, encouraging signs that the kind of centralized, government-issue, one-size-fits-all health care favored by the Clintons, Ira Magaziner and a few other woolgatherers is, as the economists say, counter-cyclical. That means, I take it, opposite to mainstream trends and thus improbable if not downright stupid.

For this assessment we turn to MIT's *Technology Review* which seems to try, as a Harvard President proclaimed as his objective before World War II, "To humanize the scientists and Simonize the humanists." In other words, it is not a technology junkie but attempts to place humanity and machines in a rational context.

In the July issue, Mitchel Resnick, an assistant professor in the MIT media laboratory who specializes in the development of computational tools to help people learn new things in new ways, confirms what we have all seen — that centralization is almost everywhere *kaput*. All the trend lines cited by Prof. Resnick are headed out from the center, not towards it.

His article, "Changing the Centralized Mind," notes the collapse of centralized power and structure in the Soviet union, the decision by the computer giant IBM to divide the huge company, which had fallen on hard times, into a dozen semi-autonomous units, and so on.

In noting powerful decentralizing forces at work in the world, he refers to the models in science: that when armies of antibodies seek out bacteria in a systematic, coordinated attack they have no centralized general staff in charge.

Neither do flocks of birds and schools of fish. Yet individuals within them manage to work together pretty well. The analogs in human society are everywhere, he says, giving force and direction to "a broad decentralization trend that is sweeping through many different domains."

One major example is education, where the long trend toward centralized authority is being reversed, as "school-based management moves decision-making authority from state and district offices to individual schools." But resistance to decentralization is often very strong:

"Even as the influence of decentralized ideas grows in many disciplines, a deep-seated resistance to such ideas remains. People seem to have strong attachments to centralized ways of thinking, assuming that every pattern must have a single cause, an ultimate controlling fact....

"A similar bias toward centralized theories can be seen throughout the history of science, with scientists remaining committed to centralized explanations even in the face of discrediting evidence....

"By clinging to this centralized mindset to explain all phenomena, politicians, managers and scientists are working with blinders on, focusing on centralized solutions even when decentralized approaches might be more appropriate, robust or reliable."

Prof. Resnick, like others, blames the centralized

mindset on Sir Isaac Newton, whose paradigm for the universe was a clocklike mechanism. "Newton's world is ruled by a centralized notion of cause and effect — one gear turns, which makes another gear turn, and so on...."

If that sounds like a description of the involute Clinton/ Magaziner health reform plan, it is probably more than coincidence. For 300 years, the Newton paradigm has held sway, in science and in the culture at large. But:

"Researchers now view a wide range of systems — everything from bird flocks to immune responses — less like clockwork mechanisms and more like complex ecosystems controlled by decentralized interactions and feedbacks."

Which seems to me a fair description of medicine before the planners arrived to tell us we are lost without their central command & control.

It just might be that this trend away from central control will prove to be our life jacket as they try to herd us into the sea.

We can best reaffirm the vital importance of the totally decentralized, highly personalized nature of patient care by intensifying the practice of what we preach — individualized, focused, one-on-one. No microchip can ever supplant that.

Individualism made American medicine the finest in the world. Now idiot theoreticians say it needs to be fixed — by collectivization. Tell me, who's crazy?

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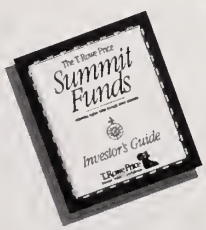
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My Helicopter Ambulance Flight

W. Foster Eich, M.D.

Nowadays helicopter ambulances are a dime a dozen. No less than four helicopter ambulance services regularly transport from our regional hospital to the metropolitan hospitals in the neighboring university cities, and two others (a little farther off) send us clipboards and pens with their 800 numbers—just so we will know that they are there if we need them. When they come for a patient they bring a flight nurse and sometimes a physician. And they are equipped with all the technology to make the aircraft an airborne intensive care unit. Quite a change from the helicopter "ambulance" flight I made 25 years ago!

Back than I was a first-year pediatrics resident on the newborn rotation at a Naval hospital. The wife of one of my fellow residents had just borne a strapping, beautiful baby boy. By the next morning, this sturdy baby had developed respiratory distress and turned an ashy blue-gray color. When I arrived at the nursery for morning rounds, the cardiologist and the attending pediatrician were already evaluating the baby. After much grave discussion and study of the EKG and chest film (while I made the routine nursery rounds) they called me over. "The baby has a hypoplastic left heart, we think. There's nothing that can be done about it. But we could be wrong. We're going to send the baby to a pediatric cardiologist with cardiac surgical facilities for further evaluation. The nearest is at Bethesda Naval Hospital. We want you to go with the baby," they said.

Rapid transportation by air is no problem in the Navy; the hospital administrative officer just calls the duty officer of the nearest Naval Air command, and it is as good as done. Navy pilots like to fly medical evacuation flights; it is a welcome change from their usual routine, and it gives them a sense of helping to make a difference in somebody's life.

Within the hour I was at the hospital baseball field, waiting for a helicopter to pick us up. Soon it came in view; a big, brown, loud machine with "USN" painted proudly on the side. I boarded the chopper, and soon we had the transport isolette (an old Armstrong unit) strapped down in the center of the cargo space. I noticed a large door on the side of the 'copter, with a winch and several pieces of heavy machinery aboard. "This is a minesweeping helicopter," the aircrewman explained. "We were just out on a practice exercise and Fleet Air called us to come for the transport."

As we got the baby all ready to go, the pilot said, "I see the baby needs oxygen, Doc. I'll fly real low to keep a good atmospheric pressure, so he'll have plenty of 0_2 partial pressure." "Not too low, please!" I answered. The pilot chuckled at my discomfiture. "Sure, about 500 feet. I'll be high enough."

I put on my hearing protectors—the helicopter had an internal sound level of 120 db. plus, and without hearing protectors a flight would ruin your hearing very quickly!—and settled back to watch my patient. "Watch" is all I could do; I couldn't auscultate his heart or lungs, obviously. I couldn't even feel the cardiac impulse because of the massive vibration in the aircraft. In fact, even watching wasn't very easy; the vibration was so bad the baby and the isolette even *looked* fuzzy.

But at least we were on the way! I turned the baby's oxygen flow up a bit, to be sure of giving him enough oxygen; that was in the days before portable oxygen monitors were available. About all I would have been able to do if the baby had suddenly worsened would have been to watch him die. I was able to suction his airway with a DeLee trap when he began to cough up blood–tinged froth. I spent most of the time praying—"God, please don't let him die before we get there! Not on my shift, please!"

The trip was relatively uneventful, until about an hour and a half had gone by. Then I noticed that the pressure was beginning to drop in the oxygen bottle. I was fast running out of oxygen! Maybe turning the oxygen flow up a little higher wasn't such a good idea after all! But surely we would soon be landing at the hospital!

In a few minutes, just as the O_2 pressure began to drop precipitously, I realized that we were landing at a large airport. That didn't make sense; we were supposed to land directly at Bethesda Naval Hospital. When the engines shut down, the pilot explained, "Doc, our radar and long-range radio are out. We had to fly Visual Flight Rules and land at the airport. But don't worry, we called ahead on the radio and there is an ambulance waiting."

"I sure hope they have oxygen!" I said, just as my bottle went dry.

We quickly moved the baby into the ambulance, and fortunately they did have oxygen. "Stay close to the duty office, Doc," the pilot said. "We may fly over to

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† Relief began in 13% of treated patients vs 4% of placebo-treated patients within 30 minutes (P=.04). At 2 hours, 48% of patients receiving placebo experienced relief. Distribution of onset times was significantly earlier for CLARITIN Tablets vs placebo (P=.03).

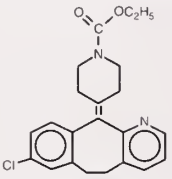
Please see following page for brief summary of Prescribing Information.

CLARITIN®
brand of loratadine
TABLETS
Long-Acting Antihistamine

PRODUCT INFORMATION

DESCRIPTION CLARITIN Tablets contain 10 mg micronized loratadine, an antihistamine, to be administered orally. They also contain the following inactive ingredients: corn starch, lactose, and magnesium stearate.

Loratadine is a white to off-white powder not soluble in water, but very soluble in acetone, alcohol, and chloroform. It has a molecular weight of 382.89, and empirical formula of $C_{22}H_{23}ClN_2O_2$, its chemical name is ethyl 4-(8-chloro-5,6-dihydro-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-ylidene)-1-piperidinecarboxylate and has the following structural formula:



CLINICAL PHARMACOLOGY Loratadine is a long-acting tricyclic antihistamine with selective peripheral histamine H_1-receptor antagonistic activity.

Human histamine skin wheal studies following single and repeated 10 mg oral doses of CLARITIN Tablets have shown that the drug exhibits an antihistaminic effect beginning within 1 to 3 hours, reaching a maximum at 8 to 12 hours and lasting in excess of 24 hours. There was no evidence of tolerance to this effect after 28 days of dosing with CLARITIN Tablets.

Pharmacokinetic studies following single and multiple oral doses of loratadine in 115 volunteers showed that loratadine is rapidly absorbed and extensively metabolized to an active metabolite (descarboethoxyloratadine). The specific enzyme systems responsible for metabolism have not been identified. Approximately 80% of the total dose administered can be found equally distributed between urine and feces in the form of metabolic products after 10 days. The mean elimination half-lives found in studies in normal adult subjects (n = 54) were 8.4 hours (range = 3 to 20 hours) for loratadine and 28 hours (range = 8.8 to 92 hours) for the major active metabolite (descarboethoxyloratadine). In nearly all patients, exposure (AUC) to the metabolite is greater than exposure to parent loratadine.

In a study involving twelve healthy geriatric subjects (66 to 78 years old), the AUC and peak plasma levels (Cmax) of both loratadine and descarboethoxyloratadine were significantly higher (approximately 50% increased) than in studies of younger subjects. The mean elimination half-lives for the elderly subjects were 18.2 hours (range = 6.7 to 37 hours) for loratadine and 17.5 hours (range = 11 to 38 hours) for the active metabolite.

Loratadine, dosed once daily, had reached steady-state by the fifth daily dose. The pharmacokinetics of loratadine and descarboethoxyloratadine are dose independent over the dose range of 10 to 40 mg and are not significantly altered by the duration of treatment.

In the clinical efficacy studies, CLARITIN Tablets were administered before meals. In a single-dose study, food increased the AUC of loratadine by approximately 40% and of descarboethoxyloratadine by approximately 15%. The time to peak plasma concentration (Tmax) of loratadine and descarboethoxyloratadine was delayed by 1 hour with a meal. Although these differences would not be expected to be clinically important, CLARITIN Tablets should be administered on an empty stomach.

In patients with chronic renal impairment (Creatinine Clearance ≤ 30 mL/min) both the AUC and peak plasma levels (Cmax) increased on average by approximately 73% for loratadine; and approximately by 120% for descarboethoxyloratadine, compared to individuals with normal renal function. The mean elimination half-lives of loratadine (7.6 hours) and descarboethoxyloratadine (23.9 hours) were not significantly different from that observed in normal subjects. Hemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite (descarboethoxyloratadine) in subjects with chronic renal impairment.

In patients with chronic alcoholic liver disease the AUC and peak plasma levels (Cmax) of loratadine were double while the pharmacokinetic profile of the active metabolite (descarboethoxyloratadine) was not significantly changed from that in normals. The elimination half-lives for loratadine and descarboethoxyloratadine were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

There was considerable variability in the pharmacokinetic data in all studies of CLARITIN Tablets, probably due to the extensive first-pass metabolism. Individual histograms of area under the curve, clearance, and volume of distribution showed a log normal distribution with a 25-fold range in distribution in healthy subjects.

Loratadine is about 97% bound to plasma proteins at the expected concentrations (2.5 to 100 ng/mL) after a therapeutic dose. Loratadine does not affect the plasma protein binding of warfarin and digoxin. The metabolite descarboethoxyloratadine is 73% to 77% bound to plasma proteins (at 0.5 to 100 ng/mL).

Whole body autoradiographic studies in rats and monkeys, radiolabeled tissue distribution studies in mice and rats, and *in vivo* radioligand studies in mice have shown that neither loratadine nor its metabolites readily cross the blood-brain barrier. Radioligand binding studies with guinea pig pulmonary and brain H_1-receptors indicate that there was preferential binding to peripheral versus central nervous system H_1-receptors.

Clinical trials of CLARITIN Tablets involved over 10,700 patients who received either CLARITIN Tablets or another antihistamine and/or placebo in double-blind randomized controlled studies. In placebo-controlled trials, 10 mg once daily of CLARITIN Tablets was superior to placebo and similar to clemastine (1 mg BID) or terfenadine (60 mg BID) in effects on nasal and non-nasal symptoms of allergic rhinitis. In these studies, somnolence occurred less frequently with CLARITIN Tablets than with clemastine and at about the same frequency as terfenadine or placebo. In studies with CLARITIN Tablets at doses 2 to 4 times higher than the recommended dose of 10 mg, a dose-related increase in the incidence of somnolence was observed. Therefore, some patients, particularly those with hepatic or renal impairment and the elderly, may experience somnolence.

In a study in which CLARITIN Tablets were administered at 4 times the clinical dose for 90 days, no clinically significant increase in the DTc was seen on ECGs.

INDICATIONS AND USAGE CLARITIN Tablets are indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis.

CONTRAINDICATIONS CLARITIN Tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients.

PRECAUTIONS **General:** Patients with liver impairment should be given a lower initial dose (10 mg every other day) because they have reduced clearance of CLARITIN Tablets.

Drug Interactions: The coadministration of a single 20 mg dose of CLARITIN Tablets (double the recommended daily dose) and a 200 mg dose of ketoconazole twice daily to 12 subjects resulted in increased plasma concentrations of loratadine (180% increase in AUC) and its active metabolite, descarboethoxyloratadine (56% increase in AUC). However, no related changes were noted in the DTc on ECGs taken at 2, 6, and 24 hours after the coadministration of loratadine and ketoconazole. Also, there were no significant differences in clinical adverse events between CLARITIN Tablet groups with or without ketoconazole.

Other drugs known to inhibit hepatic metabolism should be coadministered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received macrolide antibiotics, cimetidine, ranitidine, or theophylline along with CLARITIN Tablets in controlled clinical trials is too small to rule out possible drug-drug interactions. There does not appear to be an increase in adverse events in subjects who received oral contraceptives and CLARITIN Tablets compared to placebo.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In an 18-month oncogenicity study in mice and a 2-year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg (mice) and 25 mg/kg (rats). In the carcinogenicity studies, pharmacokinetic assessments were carried out to determine animal exposure to the drug. AUC data demonstrated that the exposure of mice given 40 mg/kg of loratadine was 3.6 (loratadine) and 18 (active metabolite) times higher than a human given 10 mg/day. Exposure of rats given 25 mg/kg of loratadine was 28 (loratadine) and 67 (active metabolite) times higher than a human given 10 mg/day. Male mice given 40 mg/kg had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg. The clinical significance of these findings during long-term use of CLARITIN Tablets is not known.

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Loratadine administration produced hepatic microsomal enzyme induction in the mouse at 40 mg/kg and rat at 25 mg/kg, but not at lower doses.

Decreased fertility in male rats, shown by lower female conception rates, occurred at approximately 64 mg/kg and was reversible with cessation of dosing. Loratadine had no effect on male or female fertility or reproduction in the rat at doses of approximately 24 mg/kg.

Pregnancy Category B: There was no evidence of animal teratogenicity in studies performed in rats and rabbits. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CLARITIN Tablets should be used during pregnancy only if clearly needed.

Nursing Mothers: Loratadine and its metabolite, descarboethoxyloratadine, pass easily into breast milk and achieve concentrations that are equivalent to plasma levels with an AUC_{milk}/AUC_{plasma} ratio of 1.17 and 0.85 for the parent and active metabolite, respectively. Following a single oral dose of 40 mg, a small amount of loratadine and metabolite was excreted into the breast milk (approximately 0.03% of 40 mg over 48 hours). A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when CLARITIN Tablets are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS Approximately 90,000 patients received CLARITIN Tablets 10 mg once daily in controlled and uncontrolled studies. Placebo-controlled clinical trials at the recommended dose of 10 mg once a day varied from 2 weeks' to 6 months' duration. The rate of premature withdrawal from these trials was approximately 2% in both the treated and placebo groups.

REPORTED ADVERSE EVENTS WITH AN INCIDENCE OF MORE THAN 2% IN PLACEBO-CONTROLLED ALLERGIC RHINITIS CLINICAL TRIALS

PERCENT OF PATIENTS REPORTING

	LORATADINE 10 mg OD n = 1926	PLACEBO n = 2545	CLEMASTINE 1 mg BID n = 536	TERFENADINE 60 mg BID n = 684
Headache	12	11	8	8
Somnolence	8	6	22	9
Fatigue	4	3	10	2
Dry Mouth	3	2	4	3

Adverse event rates did not appear to differ significantly based on age or race, although the number of non-white subjects was relatively sm

In addition to those adverse events reported above, the following a events have been reported in 2% or fewer patients.

Autonomic Nervous System Altered salivation, increased swe altered lacrimation, hypoesthesia, impotence, thirst, flushing.

Body As A Whole Conjunctivitis, blurred vision, earache, eye tinnitus, asthenia, weight gain, back pain, leg cramps, malaise, chest rigors, fever, aggravated allergy, upper respiratory infection, angioneu edema.

Cardiovascular System Hypotension, hypertension, palpitations cope, tachycardia.

Central and Peripheral Nervous System Hyperkinesia, blepharos paresthesia, dizziness, migraine, tremor, vertigo, dysphonia.

Gastrointestinal System Abdominal distress, nausea, vomiting lence, gastritis, constipation, diarrhea, altered taste, increased ap anorexia, dyspepsia, stomatitis, toothache.

Musculoskeletal System Arthralgia, myalgia.

Psychiatric Anxiety, depression, agitation, insomnia, paroniria, an impaired concentration, confusion, decreased libido, nervousness.

Reproductive System Breast pain, menorrhagia, dysmenorrhea, va

Respiratory System Nasal dryness, epistaxis, pharyngitis, dy nasal congestion, coughing, rhinitis, hemoptysis, sinusitis, sneezing chospasm, bronchitis, laryngitis.

Skin and Appendages Dermatitis, dry hair, dry skin, urticaria, ras ritus, photosensitivity reaction, purpura.

Urinary System Urinary discoloration, altered micturition.

In addition, the following spontaneous adverse events have been re rarely during the marketing of loratadine: peripheral edema; abnorm patic function, including jaundice, hepatitis, and hepatic necrosis; al seizures; breast enlargement; erythema multiforme; and anaphylaxis

DRUG ABUSE AND DEPENDENCE There is no information to indic abuse or dependency occurs with CLARITIN Tablets.

OVERDOSAGE Somnolence, tachycardia, and headache have b ported with overdoses greater than 10 mg (40 to 180 mg). In the e overdosage, general symptomatic and supportive measures sho instituted promptly and maintained for as long as necessary.

Treatment of overdosage would reasonably consist of emesis syrup), except in patients with impaired consciousness, followed by ministration of activated charcoal to absorb any remaining drug. If v is unsuccessful, or contraindicated, gastric lavage should be per with normal saline. Saline cathartics may also be of value for rapid of bowel contents. Loratadine is not eliminated by hemodialysis. known if loratadine is eliminated by peritoneal dialysis.

Oral LD_{50} values for loratadine were greater than 5000 mg/kg in r mice. Doses as high as 10 times the recommended clinical doses s no effects in rats, mice, and monkeys.

DOSAGE AND ADMINISTRATION Adults and children 12 years of a over: One 10 mg tablet daily on an empty stomach.

In patients with liver failure, 10 mg every other day should be th ing dose

HOW SUPPLIED CLARITIN Tablets, 10 mg, white to off-white com tablets; impressed with the product identification number "458" side; and "CLARITIN 10" on the other; high density polyethylene plas tles of 100 (NDC 0085-0458-03). Also available, CLARITIN Unit-of-Us ages of 14 tablets (7 tablets per blister card) (NDC 0085-0458-01) tablets (10 tablets per blister card) (NDC 0085-0458-05); and 10 x 1 Unit Dose-Hospital Pack (NDC 0085-0458-04).

Protect Unit-of-Use packaging and Unit Dose-Hospital Pa excessive moisture. Store between 2° and 30°C (36° and 86°F).

Schering®
Schering Corporation
Kenilworth, NJ 07033 USA

Rev. 9/93

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CLARITIN®
brand of loratadine
TABLETS
Long-Acting Antihistamine

BRIEF SUMMARY
(For full Prescribing Information, see package insert.)

INDICATIONS AND USAGE
CLARITIN Tablets are indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis.

CONTRAINDICATIONS
CLARITIN Tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients.

PRECAUTIONS
General: Patients with liver impairment should be given a lower initial dose (10 mg every other day) because they have reduced clearance of CLARITIN Tablets.

Drug Interactions: The coadministration of a single 20 mg dose of CLARITIN Tablets (double the recommended daily dose) and a 200 mg dose of ketoconazole twice daily to 12 subjects resulted in increased plasma concentrations of loratadine (180% increase in AUC) and its active metabolite, descarboethoxyloratadine (56% increase in AUC). However, no related changes were noted in the QTc on ECGs taken at 2, 6, and 24 hours after the coadministration of loratadine and ketoconazole. Also, there were no significant differences in clinical adverse events between CLARITIN Tablet groups with or without ketoconazole.

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Cardiovascular System: Hypotension, hypertension, palpitations, syncope, tachycardia.
Central and Peripheral Nervous System: Hyperkinesia, blepharospasm, paresthesia, dizziness, migraine, tremor, vertigo, dysphonia.
Gastrointestinal System: Abdominal distress, nausea, vomiting, flatulence, gastritis, constipation, diarrhea, altered taste, increased appetite, anorexia, dyspepsia, stomatitis, toothache.
Musculoskeletal System: Arthralgia, myalgia.
Psychatric: Anxiety, depression, agitation, insomnia, paroniria, amnesia, impaired concentration, confusion, decreased libido, nervousness.
Reproductive System: Breast pain, menorrhagia, dysmenorrhea, vaginitis.
Respiratory System: Nasal dryness, epistaxis, pharyngitis, dyspnea, nasal congestion, coughing, rhinitis, hemoptysis, sinusitis, sneezing, bronchospasm, bronchitis, laryngitis.
Skin and Appendages: Dermatitis, dry hair, dry skin, urticaria, rash, pruritus, photosensitivity reaction, purpura.
Urinary System: Urinary discoloration, altered micturition.

In addition, the following spontaneous adverse events have been reported rarely during the marketing of loratadine: peripheral edema, abnormal hepatic function, including jaundice, hepatitis, and hepatic necrosis, alopecia, seizures, breast enlargement, erythema multiforme, and anaphylaxis.

OVERDOSAGE
Somnolence, tachycardia, and headache have been reported with overdoses greater than 10 mg (40 to 180 mg). In the event of overdosage, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

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Reference

1. Bédard P-M, Del Carpio J, Drouin MA, et al. Onset of action of loratadine and placebo and other efficacy variables in patients with seasonal allergic rhinitis. Clin Ther. 1992;14:268-275.

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Andrews Air Force Base and get our radios fixed. Or we may stay overnight. We'll call and let you know."

I got the baby to the nursery and turned him over to the nursery resident, still alive. After he and the chief resident got the baby admitted, the chief resident gave me a tour of the hospital. While he and I were sitting at the supper table, drinking coffee and talking pediatrics, I was paged to the duty office. The pilot had decided to go home.

When I got out to the airport, the pilot and co-pilot were standing by the 'copter looking up at the sky. "We didn't get our electronics fixed, Doc, but the fog is supposed to lift. We should be able to fly back to Norfolk Naval Air Station by VFR. We're going to watch and see." They pilot and copilot stood looking up into the sky. In about five minutes, one of the pilots said, "OK, I see a star, let's go!" Quickly the two pilots got into their seats and the crewman got his fire extinguisher out and stood with it aimed at the engines. That didn't reassure me a bit! "Just routine procedure, Doc. Just to be sure it doesn't catch fire!" the pilot reassured me. I was glad it wouldn't catch fire!

The engines cranked and cranked, groaned and wheezed, but they didn't catch fire. In fact, they didn't do much of anything.

They wouldn't start. Finally the pilots quit trying and told me, "This bird usually flies off the deck of a mine sweeper. We just plug into the electrical power on the deck. It's not really good at starting off its own batteries." They made a quick radio call, and soon an airport generator truck was there. They plugged in, and in seconds the turbines were whining.

I settled back in the dark machine with my ears protected by the hearing protectors and slept. There wasn't much else to do as we flew to the Naval Air Station at Norfolk. Soon I realized that the sound of the machine was changing, so I woke up and looked out to see that we were landing at an airport with a big "ESSO" sign. "Funny," I though, "I didn't know that Naval Air Stations sold ESSO gasoline." After we landed the pilot explained that the fog had closed in again "but we finally found an airport. I think we're in Richmond."

We had flown out on payday, and none of us had any money except the enlisted aircrewman. All of us had left our paychecks in Norfolk except him. He had cashed his, but it wasn't very much. We did have enough money to get a cab and find a motel. I charged the motel bill on my credit card.

The pilots called on the telephone to check in with their squadron duty officer. They planned to have him call their families and tell them they wouldn't be home that night. "Want them to call your wife, Doc? It will save you a long distance call home," the pilot asked. "Sure, thanks," I answered. So their duty officer called my wife to tell her I was OK, but wouldn't be home. The call went something like this:

"Mrs. Eich? This is the squadron VH-umpty ump duty office. Your husband went on a flight with one of our helicopters today. We just wanted you to know that he is all right. Everything is OK."

"What do you mean, everything is OK?" Ginger asked. "What happened? Where is he?" (She's usually not a worrier, but somehow this got to her. What was I all right from?)

"Oh, we can't tell you that, Ma'am. But he's all right. He won't be home tonight, but he will be home."

The pilot's wives knew that this didn't mean anything unusual; they got calls like this all the time. But Ginger sat on the side of the bed all night worrying about what had happened, what I was OK from, and why couldn't they tell her. Had we crashed? Was I in a burn unit somewhere? Had we been diverted to a ship which was on its way to Viet Nam? When would she see me again?

The next morning at breakfast, we were really a motley crew; three naval aviators in flight suits, and one navy doctor in dress blues, all disheveled, unkempt, and unshaven. I was glad we weren't having to stand inspection!

The flight back to Portsmouth was uneventful. It was early fall, and the pilot flew just above the treetops so I could enjoy the glory of the fall foliage. After a short flight I was back at the baseball field of the Naval Hospital.

When I got back to the hospital, I learned that our cardiologist had been right; the baby had a hypoplastic left heart.

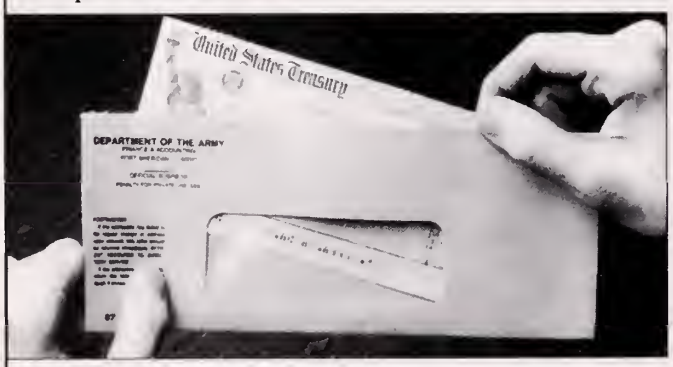
He had lived through the night, but died shortly before I got back to Portsmouth.

My fellow resident and his wife really seemed to appreciate my going with their baby. I didn't really feel that I had done very much, but at least we had given it our best shot.

Nowadays when a baby had to be transported, I watch the beautiful "Lifesaver" helicopter land on the roof of our hospital and the flight nurse connect the baby to a cardiopulmonary monitor, pulse oximeter, respirator, infusion pump, and put an oxygen analyzer in the transport unit before they take off. I am not nostalgic at all. I do not care to go back to "the way we used to do it in the old days!"

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Newborn Congenital Anomalies in Jefferson County, Alabama

Wayne H. Finley, Ph.D., M.D.; Tracy M. Hall, MS; David C. Hurst, Ph.D.; Sara C. Finley, M.D.; Edward D. Conner, M.D.; Clyde M. Barganier, DrPH; JoAnn Wiedmeyer, BSN.

This article is a revised and corrected version of the first printing in Alabama Medicine *Vol. 63. No. 8. That earlier printing was critically flawed by a profusion of typographical errors for which the authors were totally blameless.–Ed.*

Introduction:

Congenital anomalies have become a leading cause of infant morbidity and mortality in this country and those newborns affected require significant health resources.[1,2] Studies of frequencies of congenital anomalies have often been retrospective and have relied upon multiple sources such as birth certificates and hospital records. In 1985 the Jefferson County Medical Society organized a surveillance program to monitor all hospital births and to document congenital anomalies observed in infants born in Jefferson County, Alabama during a 2-year period. This prospective study was undertaken with cooperation of the 11 hospitals with delivery services, and anomalies were recorded by a single maternal and child health nurse. The computerized database generated could be used to estimate health resources required for management, provide information for follow-up of affected infants, possibly detect sudden changes in birth defect incidences, and to help identify research directions for prevention of birth defects. Some of these data have been reported. [3,4]

Methodology

A survey of all newborns of 20 or more weeks gestation was conducted in Jefferson County, Alabama hospitals for a 2-year period (January 1, 1986-December 31, 1987). Information about infants noted to have a congenital anomaly was obtained weekly at the hospital of birth, and 99.7% of births occurred in or en route to one of the 11 hospitals.

From the Laboratory of Medical Gentics, Department of Pediatrics (Drs. Finley and Miss Hall), Department of Biostatistics and Biomathematics (Dr. Hurst), University of Alahama at Birmingham, Birmingham; St. Vincent's Hospital, Birmingham (Dr. Conner), Alabama State Department of Public Health, Montgomery, Alabama (Dr. Barganier); Jefferson County Medical Society, Birmingham, Alahama (Ms. Wiedmeyer). Reprint request: Wayne H. Finley, PhD, MD, UAB, Birmingham, AL 35294.

The study group consisted of 27,904 births of which 27,561 were live-born. Of the live-born infants 65% were white and 35% were non-white (black). The same nurse reviewed delivery records, examined affected infants if possible, and obtained autopsy reports to complete the data sheet. The minimum data recorded were birthdate; birth weight; sex; gestational age; discharge status; maternal race, age, parity and zip code; and hospital of birth. Code numbers were assigned the observed congenital anomalies in accordance with the International Classification of Disease (ICD).

Results

The number of births in Jefferson County during 1986-1987 represented 23.5% of the total births in Alabama (Table 1). The total white births in the county were 18,081 (23.3% of the State's white births) and the total non-white births were 9,823 (23.7% of the State's non-white births).

Some comparisons of data in Tables 1-5 are:

Non-white stillbirths (17.2/1,000) > white stillbirths (9.6/1,000) ($p<.0001$)

Non-white male stillbirths (17.7/1,000) > white male stillbirths (11.3/1,000) ($p<.0001$)

Non-white female stillbirths (16.7/1,000) > white female stillbirths (7.8/1,000) ($p<.0001$)

Non-white births with congenital anomalies (25.8/1,000) > white births with congenital anomalies (22.4/1,000) ($p< . 01$)

Non-white livebirths with congenital anomalies (23.9/1,000) > white livebirths with congenital anomalies (19.0/1,000) ($p<.002$)

White male livebirths with congenital anomalies (24.5/1,000) > white female livebirths with congenital anomalies (13.3/1,000) ($p<.0001$)

Non-white male livebirths with congenital anomalies (27.2/1,000) > non-white female livebirths with congenital anomalies (20.5/1,000) ($p<.002$)

White stillbirths with congenital anomalies (2.2/1,000) = non-white stillbirths with congenital anomalies (2.2/1,000)

Anencephaly in white livebirths (2.3/10,000) >

Table 1. Jefferson County, Alabama Births (1986-1987)

Category	All Births No.	%	Live Births No.	%	Stillbirths No.	%	Frequency (10^3)
White Male	9,248	33.3	9,179	33.3	105	30.6	11.3
White Female	8,797	31.5	8,728	31.7	69	20.1	7.8
Total White Births	18,081	64.8	17,907	65.0	174	50.7	9.6
Non-White Male	4,971	17.8	4,883	17.7	88	25.7	17.7
Non-White Female	4,852	17.4	4,771	17.3	81	23.6	16.7
Total Non-White Births	9,823	35.2	9,654	35.0	169	49.3	17.2
Total Births	27,904		27,561		343		12.3

Total Alabama Births (1986)	59,441	(Whites 38,632; Others 20, 809)[5]
Total Alabama Births (1987)	59,558	(Whites 38,826; Others 20,732)[6]
Total Alabama Births (1986, 1987)	118,999	(Whites 77,458; Others 41,541)

Table 2. Number of Newborn Infants with Congenital Anomalies in Jefferson County, Alabama (1986-1987)

Category	All Births (Affected) No.	%	Frequency (10^3)	Live Births (Affected) No.	%	Frequency (10^3)	Stillbirths (Affected) No.	%	Frequency (10^3)
White Male	225	38.8	27.5	225	39.3	24.5	17	27.4	1.8
White Female	150	22.8	17.1	116	20.3	13.3	22	35.5	2.5
Total White Births	405	61.6	22.4	341	59.6	19.0	39	62.9	2.2
Non-White Male	145	22.0	29.2	133	23.3	27.2	10	16.1	2.0
Non-White Female	108	16.4	22.3	98	17.1	20.5	8	12.9	1.6
Total Non-White Births	253	38.4	25.8	231	40.4	23.9	22*	35.5	2.2
Total Affected	668*		23.9	572		20.8	62*		

*Status unknown for 10 affected infants

Table 3. Congenital Anomalies in Live Born Infants (per 10,000 births)

	This Study (1986-1987)	Atlanta[7] (1967-1968)	U.S.A.[1] (1981-1986)
Anencephaly			
White	2.3	10.6	3.0
Blacks	1.0	1.4	2.1
Spina Bifida			
Whites	15.0	17.5	5.1
Blacks	9.3	9.8	3.3
Hydrocephalus			
Whites	15.6		5.4
Blacks	14.5		8.1
Cleft Lip/Cleft Palate			
Whites	14.0	11.1	15.6
Blacks	10.4	4.2	8.1
Heart Malformations			
Whites	16.8	22.8	50.7
Blacks	14.5	22.4	77.7
Club Foot			
Whites	14.5	31.8	27.5
Blacks	11.4	25.2	19.9
Hypospadias			
Whites	31.6		32.7
Blacks	24.6		24.6
Polydactyly			
Whites	14.5	11.7	
Blacks	118.1	93.9	
Down Syndrome			
Whites	11.2		8.5
Blacks	8.3		6.5

Table 4. Incidences of Specific Congenital Anomalies in Maternal Age Groups for Jefferson County, Alabama (1986-1987)

Rate (10^3)	All Ages	<15	15-19	20-24	25-29	30-34	35-39	>40
Total Anomalies	23.9	15.3	24.4	25.9	20.3	22.8	31.5	16.8
Anencephaly	0.5		1.8	0.2	0.3			
Spina Bifida	1.3		2.3	1.7	1.0	0.6	1.3	
Hydrocephalus	1.5		2.3	1.4	0.9	0.8	2.6	
Cleft Lip/ Cleft Palate	1.7		1.1	0.9	1.9	2.3	0.6	
Omphalocele	1.0		1.3	1.7	0.8	0.8	0.6	
Heart Malformations	2.2		1.5	2.3	1.1	2.8	5.1	5.6
Club Foot	1.6		2.5	1.6	1.3	2.5	1.9	
Hypospadias	2.9		1.5	2.6	1.3	0.9	1.3	
Polydactyly	5.0	7.6	5.3	5.3	3.0	3.2	3.2	
Syndactyly	1.0		1.3	1.2	1.1	0.6	0.6	
Down Syndrome	1.3		0.3	0.6	0.6	2.3	8.3	5.6

Table 5. Incidence (10^4) of Congenital Anomalies in Liveborn Infants in Jefferson County, Alabama and Projections for Alabama*

	Frequency (Jefferson Co.) 1986-1987			Number Suspected (Alabama) (1986-1987)		
Anencephaly		M	F		M	F
Whites	2.3	1.1	3.4	17.8	4.4	12.8
Blacks	1.0	2.0	0.0	4.2	4.2	0.0
Spina Bifida						
Whites	15.0	12.0	18.3	116.3	47.6	69.0
Blacks	9.3	12.3	6.3	38.6	25.9	13.0
Hydrocephalus						
Whites	15.6	17.4	13.7	120.9	69.0	51.7
Blacks	14.5	14.3	14.7	60.2	30.1	30.3
Cleft Lip/ Cleft Palate						
Whites	14.0	16.3	11.5	108.5	64.6	43.4
Blacks	10.4	12.3	8.4	43.2	25.9	17.3
Heart Malformations						
Whites	16.8	22.9	24.1	130.2	90.7	90.9
Blacks	14.5	20.5	18.9	60.2	43.2	38.9
Club Foot						
Whites	14.5	21.8	6.9	112.4	86.4	26.1
Blacks	11.4	18.4	4.2	47.3	38.8	8.6
Hypospadias						
Whites	31.6	31.6		244.9	125.2	
Blacks	24.6	24.6		103.1	51.8	
Polydactyly						
Whites	14.5	22.9	5.7	112.4	90.7	21.5
Blacks	118.1	124.9	111.1	490.1	263.1	228.7
Down Syndrome						
Whites	11.2	15.2	6.9	86.8	60.2	26.0
Blacks	8.2	6.1	10.5	34.4	12.8	21.6

*Based on combined 1986-1987 data

White births	77,458
Black births	41,541
White male births	39,627
White female births	37,723
Black male births	21,063
Black female births	20,587

anencephaly in black livebirths (1.0/10,000) ($p<0.01$)

Spina bifida in white livebirths (15.0/10,000) > spina bifida in black livebirths (9.3/10,000) ($p<0.01$)

Hypospadias in white male livebirths (31.6/10,000) > hypospadias in black male livebirths (24.6/10,000) ($p<0.0003$)

Polydactyly in black livebirths (118.1/10,000) > polydactyly in white livebirths (14.5/10,000) ($p>0.0001$)

Specific malformation incidences which did not differ significantly in white and black livebirths were hydrocephalus, cleft lip/palate, heart malformations, and club foot. The higher occurrence of anomalies in stillborn white female infants (2.5/1,000) was accompanied by the lowest incidence of anomalies in liveborn white female infants (13.3/1,000).

Table 6. Births and Affected Births in Maternal Age Groups.

Maternal Ages	<15	15-19	20-24	25-29	30-34	35-39	>40
Births (%)							
White	0.1	10.5	27.6	34.3	20.8	6.1	0.6
Non-white	1.1	20.8	31.8	25.7	15.3	4.7	0.6
Combined	0.5	14.1	29.1	31.2	19.0	5.6	0.6
Affected(%)							
White	0.2	13.2	29.4	27.6	19.9	9.2	0.2
Non-white	0.4	16.9	36.2	25.6	15.7	4.7	0.4
Combined	0.3	14.6	31.9	26.9	18.4	7.4	0.5

The incidence of affected infants with younger non-white mothers was higher than in those with older white mothers (Table 6). A higher percent of non-white mothers were teenage than were white mothers. The birth rates in white mothers were higher beginning with the 25-29 age group and in black mothers in the 20-24 age group.

Approximately 10% of the total newborns weighed ≤ 2,500 grams and in this group were 28% of the affected infants (Table 7). The majority of both white and non-white infants weighed between 3,001-3,500 grams, however, 40% of white infants and only 22% of nonwhite infants weighed more than 3,500 grams. A total of 7% and 14% of white and black newborns respectively weighed ≤ 2,500 grams.

Discussion

A prospective study to determine the incidence of

Table 7. Birth Weight of Resident Infants in Jefferson County, Alabama (1986-1987)*

Birth Weight (gm)	White Births		Non-White Births		Total Births	
	No. Affected	(%)	No. Affected	(%)	No. Affected	(%)
<1,000	0.7	10.5	1.9	6.9	1.2	8.9
1,000-1,500	0.6	4.1	1.6	4.9	1.0	4.3
1,501-2,000	1.2	6.9	2.8	4.5	1.9	5.7
2,001-2,500	4.5	8.8	8.1	10.5	6.1	9.3
2,501-3,000	16.1	19.9	25.8	19.4	20.4	19.3
3,001-3,500	36.3	22.9	38.1	30.8	37.1	25.4
3,501-4,000	28.9	20.2	17.4	19.0	23.8	19.3
4,000-4,500	10.0	9.4	4.0	3.6	7.3	6.9
>4,501	1.6	1.4	0.6	0.4	1.1	1.0

*Birth weights of resident births, not of those delivered in Jefferson County hospitals with residences outside.

congenital anomalies in newborn infants in Jefferson County, Alabama was undertaken to gain experience in birth defects surveillance and to provide estimates of statewide occurrence rates. This study was encouraged by the Maternal and Child Health Committee of the Jefferson County Medical Society and the 11 Jefferson County hospitals with obstetric services. Data concerning the types and patterns of occurrence of congenital anomalies, a leading cause of infant morbidity and mortality, would aid in planning for health resources. Occurrence rates in Jefferson County, Alabama's most populous county, determined over a 2-year period, gave an opportunity to estimate number of affected infants statewide.

Distribution of specific congenital anomalies is known to differ on the basis of ethnic groups, sex, and geography[1,8,9]. It is recognized that some differences might be accounted for by variation in clinical methodology and system of recording. Differences between Alabama data and other locales could reflect gene pool differences, environmental conditions, cultural influences, access to medical care, nutrition, alcohol consumption, and other socioeconomic factors. An extension of this study would be collection of data from more rural and less industrialized areas of Alabama for comparison with Jefferson County information. Significant differences in incidences could result in specific research projects and in better planning for management of patients. Some variation has been reported in the number of affected infants among widely scattered geographical areas. However, a greater variation has been noted for selected anomalies.[10-12]

The newborn population of Jefferson County (Table 1) provided a good opportunity to compare congenital anomalies in whites with non-whites (blacks). Previous studies have shown that black infants had a higher overall frequency of congenital anomalies than whites, however, this higher incidence in blacks could be attributed to an increase in minor malformations.[1,13,14] Our study (Table 2) showed a higher incidence of affected black infants (25.8/1,000) to whites (22.4/1,000) while the national frequency was lower than both (19.7/1,000).[13] The 2-fold increase in low birth weight infants in the non-white group over the whites occurred without an appreciable difference in percent affected with congenital anomalies.

Differences in frequencies of congenital anomalies in males and females have been reported in several studies.[15,16] Our data indicated a higher occurrence of frequency of affected white males (24.5/1,000) to white females (13.3/1,000) and higher affected non-white males (27.2/1,000) to non-white females (20.5/1,000). The high frequency of anomalies (35.5/1,000) in white female stillborn infants is unexplained.

Incidences of specific anomalies differ between ethnic groups. Studies have shown that infants with multiple anomalies occur with about the same frequency in whites and blacks.[14] In our study the occurrence of stillborn infants was higher in the black group than in the white group; higher in black males than white males; and higher in black females than white females. Occurrence of stillborns with congenital anomalies was the same in black and white infants, therefore, the significant differences in black and white stillborn incidences are not explained by observable congenital anomalies. White stillborn female infants with congenital anomalies occurred at a higher incidence than either white male, black female, or black male stillbirths.

Neural tube defects, one of the most common congenital anomalies, is now receiving much attention because of the finding that preconceptual folic acid can affect the rate of occurrence.[17-19] Our data may be very important in the future to compare incidences of NTD's before and after folic acid becomes widely used. Findings of a higher incidence of anencephaly and spina bifida in white liveborn infants would justify study of dietary folic acid in both white and black mothers. Higher incidences of neural tube defects in white infants than in black infants were reported in the 1967-1968 Atlanta Study[1] and in the 1981-1986 USA study, both of which showed higher frequencies than in an Asian population[7]. At this time it is not

known to what extent prenatal detection programs in this country and others, have effected the occurrence of neural tube defects in liveborn infants.[12] Increased recurrence risks have placed neural tube defects within the multifactorial group of genetic disorders, realizing that there are both geographical and ethnic group variations in incidences.

The incidences of specific congenital anomalies occurring in the various maternal age groups are tabulated in Table 4. Incidences for specific anomalies were about the same for various age groups except for heart malformations and Down Syndrome which had higher incidences in mothers above 35 years of age.

Although some fluctuation can be expected in a particular geographical area, periodic estimates of congenital anomaly incidences could be useful for research, design of services, planning for personnel requirements, and determining the burden on families with affected members. The baseline data could be useful for various specialists and subspecialists who manage patients with congenital anomalies. A monitoring system would permit early detection of an epidemic of a rare malformation, ascertainment of gradual changes in incidences of common malformations, and design of research to evaluate genetic and environmental contributions to specific malformations. It would be of particular value to the medical genetics teams in formulating future plans if they could use these data in designing education materials for primary health providers and for reaching those Alabama families needing genetic information.

Our data were compiled economically and the procedures used could be taken as a pilot study for expansion to a regional or statewide surveillance program. Experienced personnel have the opportunity to collect valuable health data in newborn nurseries. A continuing surveillance program would be valuable to many who deal with prenatal care, poor pregnancy outcomes, recurrence risks, patient management, family counseling and follow-up.

Newborn screening information, which is already being collected, added to a registry of congenital anomalies would be helpful in establishing statewide priorities in health planning. Specialized clinical and laboratory genetic services continue to offer preventive approaches which can reduce health costs and contribute to easing the family burdens. Surveillance for congenital anomalies in infants and children will yield data important for the planning of health care reform measures.

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The Changing Relationship Between Physicians And Hospitals

*Richard J. Brockman, J.D.**
*David M. Hunt, J.D.**

In this time of health care reforrn and sweeping change in the health care industry, physicians and hospitals have begun to re-examine their relationship with one another. Increasingly, hospitals and physicians are seeking to enter into closer alliances, either through the hospital's purchase of the physician's practice or some other type of joint venture, in order to provide greater stability and a better chance of survival to both parties. The purchase by a hospital of a physician's practice can provide many benefits to both the hospital and the physician:

Benefits to Hospital

- **Expansion of services to include additional treatment modalities**
- **Ability to maintain or increase patient flow**
- **Improved negotiating position with respect to managed care contracts**
- **Increased loyalty of physician to hospital**
- **Quaility of care is enhanced by maintenance of a stable staff of physicians**

Benefits to Physician

- **Lump sum payment for hard assets of the practice**
- **Relief from administrative demands of running a business**
- **Potential increased access to patients enrolled in managed care organizations**
- **Improved relations and interaction with other disciplines**

For all of the potential advantages that hospital-physician alliances offer, however, they also raise a host of legal issues which any hospital administrator or physician who is contemplating such a relationship must consider. This outline will address three of the more important legal issues that confront hospitals and physicians in entering into these new alliances.[1] These issues are:

1) The physician's employment status after the practice acquisition or joint venture, and its effect on the hospital.
2) Compliance of the practice acquisition or joint venture with the Medicare and Medicaid Fraud and Abuse Statute, commonly referred to as the "anti-kickback" statute;
3) The effect of the practice acquisition or joint venture on the tax-exempt status of the hospital;

II. The Impact of the Physician's Employment Status after the Practice Acquisition: Independent Contractor vs. Employee.

One of the most important choices that has to be made at the outset of any physician practice acquisition or hospital-physician joint venture is what the physician's employment status will be after the acquisition or joint venture is completed. From a hospital's perspective, neither an employer-employee relationship nor an employer-independent contractor relationship is preferable in every situation. There are benefits and drawbacks to both types of relationships. Depending on the different personalities and fact situations involved in a particular transaction, a hospital will want to set up different post-acquisition relationships with physicians.

A. Physician as employee.

The primary advantage that a hospital gains from entering into an employer-employee relationship with a physician whose practice it acquires is that compliance with the Medicare and Medicaid Fraud and Abuse statute, 42 U.S.C. § 1320a-7b(b), becomes much simpler and easier.[2] This can often be a significant advantage to both the physician and the hospital.

A hospital wishing to enter into an employer-employee relationship with a physician must first overcome the problems presented by the "corporate practice of medicine" doctrine. In Alabama, the corporate practice of medicine doctrine is codified in §§ 34-24-50 through 52 *Alabama Code* (1975, as amended), which makes it a crime to practice medicine without a license. The most recent pronouncement on the appli-

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cability of this statute to hospitals which directly employ physicians was set forth in an October 21, 1992 declaratory ruling issued by the Alabama Board of Medical Examiners:

> Physicians are free to enter into contracts of employment for their professional services with professional corporations, non-profit corporations, business corporations, partnerships, joint ventures or other entities, provided however, that the physician must exercise independent judgment in matters related to the practice of medicine and that his or her actions with respect to the practice of medicine must not be subject to the control of an individual not licensed to practice medicine.

Accordingly, a hospital is free to enter into an employer-employee relationship with a physician provided that it does not seek to control the physician's independent judgment in matters related to the practice of medicine. In order to ensure compliance with § 34-24-50 et seq. it is a good idea to include a clause similar to the following clause in the employment contract between the hospital and the physician:

> PATIENT CARE DECISIONS: The employment relationship between Physician and Employer is not intended to, and shall not, impair the prerogative of the Physician to exercise his independent professional judgment in the care and treatment of all patients attended by Physician and in the determination of their appropriate medical care. Physician is expected to exercise his independent professional judgment with respect to the patient care rendered by Physician, and Physician shall exercise final authority over all medical decisions in the care and treatment of patients by the Physician.

B. Physician as independent contractor.

From a hospital's perspective, there are two very significant advantages to be gained if a physician remains an independent contractor after the hospital purchases the physician's practice. First, the classification of a physician as an independent contractor can provide significant tax advantages to a hospital. These tax advantages include not having to withhold income taxes, reduced social security taxes, lower worker's compensation premiums, and lower costs for fringe benefits such as pension contributions, vacation pay, and insurance. Even more importantly, however, a hospital can obtain some insulation from liability for a physician's negligence by maintaining an employer-independent contractor relationship with the physician. In *Humana Medical Corporation of Alabama v. Traffanstedt*, 597 So.2d 667 (Ala. 1992), the Alabama Supreme Court explained the effect of a physician's employment relationship with a hospital on the liability of the hospital for the physician's conduct. If the physician is an employee or an agent of the hospital, the Court noted that the hospital may be vicariously liable for the physician's conduct pursuant to the doctrine of *respondeat superior*.[3] *Humana*, 597 So.2d at 668. On the other hand, if the physician is an independent contractor, the Court held that the hospital cannot be liable under a *respondeat superior* theory. While the hospital may still be held liable under a "corporate negligence"[4] theory or an "ostensible agency"[5] theory, the independent contractor status of a physician provides a hospital with significant insulation from liability for the medical malpractice of the physician.

C. Determination of employment status.

Regardless of whether a hospital decides to enter into an employer-employee relationship or an employer-independent contractor relationship with a physician, it is important to be sure that the hospital's choice of relationship is respected by the courts and the Internal Revenue Service ("IRS"). Historically, Alabama courts have recognized physicians as independent contractors rather than employees of a hospital. *See Humana*, 597 So.2d at 669. The increasingly close relationship between hospitals and physicians, however, has caused a gradual erosion of this presumption of an employer-independent contractor relationship. The IRS has also begun to look with increasing skepticism on employers who classify their workers as independent contractors. Since the early 1990s the IRS has extended its regular audits to include a review of distributions to independent contractors. In the event that the IRS determines that a physician has been misclassified as an independent contractor, the penalties to a hospital can be quite severe.[6] Accordingly, a hospital must make sure that its employment relationship with a physician whose practice it acquires is carefully structured.

In determining whether the relationship between a hospital and a physician is an employer-employee relationship or an employer-independent contractor relationship, both Alabama courts and the IRS will seek to determine whether the hospital has the right to control the physician. *See Gossett v. Twin County Cable T. V., Inc.*, 594 So.2d 635 (Ala. 1992). Actual control is not the test. In examining whether there is a right of control, the courts and the IRS will examine the actual relationship between the hospital and the physician, as well as any contractual language used by the parties to describe their relationship. *Id.* The IRS has identified twenty (20) primary factors that it will use to determine if a sufficient right of control is present to create an employer-employee relationship:

- To what degree does the employer "direct" the worker?
- Under what conditions can the worker be

fired?

- Is the worker subject to a "breach of contract" charge if he or she prematurely terminates the working relationship?
- Are assistants subject to control by the employer?
- Is the worker paid per time intervals?
- Does the employer provide training?
- Is the worker distinguished from the employer's regular employees?
- Is the work performed characterized by personal service?
- Does the worker provide continuing services for the employer?
- Are work hours set by the employer?
- Are tools furnished by the employer?
- Is the work performed at the employer's place of business?
- Has the worker made significant investments in his or her business?
- Is the worker required to submit regular reports?
- Does the worker work full-time for one employer?
- Does the employer designate the order of work to be performed?
- Does the employer pay business and traveling expenses?
- Is the worker exposed to normal profit and loss risks associated with operating a business?
- Does the worker provide services to the general public?
- Does the worker provide services to more than one employer?

Revenue Ruling 87-41. By structuring its employment relationship with a physician with these factors in mind, a hospital can seek to ensure that its choice of the employment relationship it wants to have with a physician will be honored by the courts and by the IRS.

III. Compliance With the Medicare and Medicaid Fraud and Abuse Statute.

The Medicare and Medicaid Fraud and Abuse Statute, 42 U.S.C. § 1320a-7b(b) (the "anti-kickback statute"), provides that any person who knowingly and willfully offers, pays, solicits, or receives any remuneration in exchange for referring an individual for the furnishing of any item or service paid for in whole or in part by Medicare or Medicaid shall be guilty of a felony. Remuneration under the anti-kickback statute includes kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash, or in kind.[7] The penalties provided by the anti-kickback statute include criminal fines of up to $25,000, imprisonment for up to five years, exclusion from the Medicaid and Medicare programs and civil money damages.

A 1988 amendment to the anti-kickback statute required the United States Department of Health and Human Services ("HHS") to promulgate regulations outlining certain transactions which did not violate the anti-kickback statute. In 1991, HHS published final regulations listing eleven specific exceptions, known as "safe harbors," to the general prohibition against remuneration in exchange for a referral contained in the anti-kickback statute. Transactions that fall completely within one of the safe harbor provisions do not violate the anti-kickback statute[8]. While it is beyond the scope of this paper to describe all of the safe harbors, two of the safe harbors in particular are important to hospitals that are contemplating the acquisition of a physician's practice and to physicians who are contemplating the purchase of another physician's practice.

For a physician who is contemplating the purchase of another physician's practice, the most important safe-harbor provision is contained in 42 C.F.R. § 1001.952(e) (1993), which provides that payment from one health care practitioner to another for the purchase of the latter practitioner's practice is exempt from fraud and abuse scrutiny so long as the sale meets the following two requirements: (1) the period from the date of the agreement to purchase the practice and the completion of the sale of the practice is not more than one year; and (2) the selling practitioner must not be in a position to make referrals to the purchasing practitioner for more than one year after the date of the first agreement between the parties pertaining to the sale of the practice. This safe harbor provision is designed to protect a physician who wishes to sell his practice to another physician because of retirement or some other event which results in the selling physician's withdrawal from the practice of medicine in the area in which his current practice is located. It is very important to note, however, that this safe harbor provisions does not extend to the sale by a physician of his practice to a hospital.

The most important safe harbor provision to a hospital which is considering the acquisition of a physician's practice is contained in 42 C.F.R. § 1001.952(i) (1993), which provides that amounts paid by an employer to an employee under a bona fide employment relationship are not subject to fraud and abuse scrutiny. This safe harbor provides a strong incentive for a hospital to enter into an employer-employee relationship with a physician whose practice it has purchased. In one fell swoop, the hospital can avoid all of the pitfalls and problems that arise from trying to structure the acquisition of a physician's practice in such a way that it does not violate the anti-kickback statute.

If a hospital chooses to have a physician whose practice it acquires remain an independent contractor or otherwise fails to come under one of the safe harbors, the hospital must be very careful to ensure that the acquisition does not violate the anti-kickback statute. Unfortunately, there is a tremendous amount of uncertainty in this area of the law and it is often very difficult to be sure that a particular physician practice acquisition complies with the anti-kickback statute. The basic problem that the anti-kickback statute presents for hospitals wishing to acquire a physician's practice is that whenever there is a practice acquisition by a party in a position to benefit from referrals from that practice, there is a question about whether the purchase arrangement includes remuneration for future referrals. From a physician's standpoint, the payment of the full fair-market value of his practice is expected, including the value of his practice's goodwill and other intangible assets. From a hospital's standpoint, however, it may be impossible to pay the physician the full fair-market value of his practice because a portion of the practice's value may be interpreted by HHS as the physician's ability to guarantee a certain number of referrals to the hospital in the future.

In December of 1992, D. McCarty Thornton, Associate General Counsel with the Inspector General Division of HHS, wrote a letter to the IRS setting forth the position of the HHS on physician practice acquisitions. In this letter, which has come to be known as the "Thornton" letter, Mr. Thornton addressed the question of whether it was allowable for a hospital to pay full fair-market value for a physician's practice. Mr. Thornton stated that, in his opinion, the anti-kickback statute does not allow a hospital to pay a physician the full fairmarket value of the physician's practice:

> "When considering the question of fair-market value, we would note that the traditional or common methods of economic valuation do not comport with the prescriptions of the anti-kickback statute.... Accordingly, when attempting to assess the fair-market value (as that term is used in an anti-kickback analysis) attributable to a physician's practice, it may be necessary to exclude from consideration any amounts which reflect, facilitate or otherwise relate to the continuing treatment of a former practice's patients.

2 HLR 244. Mr. Thornton then goes on to state that "any amount paid in excess of the fairmarket value of the hard assets of a physician practice would be open to question." Id. Specifically, Mr. Thornton identified six intangible assets which he believed "would raise a question as to whether payment was being made for the value of a referral" if a hospital was to allocate a portion of the purchase price of a physician's practice to such an asset:

- goodwill;
- value of ongoing business unit;
- covenants not to compete;
- exclusive dealing agreements;
- patient lists; and
- patient records.

The Thornton letter's suggestion that a hospital would violate the anti-kickback statute by making any payment for the intangible assets of a physician's practice was greeted with a storm of protest from all areas of the health care industry. Physicians were particularly upset at the proposition that they would not be able to get full fair market value for their practices. Fortunately, HHS appears to have backed off somewhat from the absolute prohibition on payment for intangible assets suggested by the Thornton letter. The IRS was the first to cast some doubt on whether the broad prohibition against payment for intangible assets contained in the Thornton letter would be enforced. In two separate determination letters approving the status of tax-exempt integrated delivery systems,[10] the IRS approved physician practice acquisitions involving the purchase of a practice's intangible assets by a hospital-based foundation. In its determination letter on the Facey Medical Foundation, the IRS specifically approved of the allocation of a portion of the purchase price of a physician' s practice to patient files and records, noncompete agreements, and goodwill. Although the IRS was careful to condition its approval of the practice acquisition in question on compliance of the transaction with the anti-kickback statute, the fact that the IRS did not question the allocation of a portion of the purchase price to exactly the same intangible assets identified in the Thornton letter as "raising a question" about whether the payment for was being made in part for the value of future referrals makes it clear that there is a difference of opinion between the IRS and the HHS on the appropriate standards for approval of physician practice acquisitions.[11]

In both public remarks and published statements, Mr. Thornton himself has also backed away somewhat from the position set forth in the Thornton letter and has clarified HHS's position on payment by a hospital for the intangible assets of a physician's practice. Mr. Thornton has taken the position that payments by a hospital to a physician for the intangible assets of the practice which reflect the value of the practice to another practitioner are allowable under the anti-kickback statute. In other words, the hospital is permitted to compensate the physician whose practice it is acquiring for the value of the patient relationships to the practice itself. The hospital is not permitted, however, to pay the physician whose practice it is acquiring for the value of the referrals of the practice's patients to the hospital for ancillary services.

Although HHS's retreat from the hard line position set forth in the Thornton letter gives hospitals more leeway in structuring physician practice acquisitions, a tremendous amount of uncertainty still remains about whether a particular physician practice acquisition will comply with the anti-kickback statute. While there will always be some level of risk in a physician practice acquisition, the risks of failure to comply with the anti-kickback statute can be minimized by complying with the following general guidelines:

- Obtain an independent appraisal of the physician's practice;
- Carefully document the reasoning behind all valuation decisions;
- Minimize allocations of the purchase price to goodwill as much as possible;[12]
- Try to make an objective showing that the practice acquisition will benefit the community;
- Consider hiring the physician whose practice is being acquired as an employee of the hospital. If feasible, this will provide maximum protection under the antikickback statute;
- Seek competent legal advice in this rapidly developing area of the law.

IV. The Effect of a Physician Practice Acquisition oo the 501(c)(3) Tax-Exempt Status of a Hospital.

The majority of hospitals in the United States are organized as tax-exempt 501(c)(3)[13] corporations. As if satisfying HHS that a physician practice acquisition does not violate the antikickback statute was not hard enough, hospitals classified as 501(c)(3) corporations must also determine whether such an acquisition complies with the IRS's prohibition against private inurement. If the physician practice acquisition is not structured carefully, it can lead to the loss by the hospital of its tax-exempt status.

The basic problems hospitals face in structuring physician practice acquisitions so as not to affect their tax-exempt status arises from the very nature of their tax-exempt status. 501(c)(3) corporations are required to be organized and operated exclusively for charitable, religious, or educational purposes, and may not allow their earnings to inure to the benefit of private individuals. The prohibition against private inurement is the crux of the problem. No part of a tax-exempt hospital's net earnings may inure to any private persons, who are defined to include those persons with personal and private interest in the activities of the hospital. Physicians on the staff of a hospital are often considered by the IRS to be "insiders" for tax purposes with respect to their financial transactions with the hospital. This creates a rebuttable presumption that hospitals must overcome. While some private benefit to physicians may be acceptable in a joint venture between a hospital and several physicians, the benefit must be "incidental" to the public benefits achieved. Although there is some private benefit present in almost all hospital-physicians relationships, such as when physicians use hospital facilities at no cost, the key is to make sure that the IRS considers such private benefits incidental to the overwhelming public benefit of the hospital-physician relationship.

In 1992, the IRS issued General Counsel Memorandum ("GCM") 39862, which reversed three previously-given private letter rulings that had commonly been cited by health care providers in support of certain joint ventures with physicians. Although GCM 39862 addresses three different private letter rulings, the basic fact pattern at issue was the same. In each of the joint ventures addressed by GCM 39862, the hospital set up a partnership with several medical staff members. The hospital served as the only general partner in the partnership while the physicians were limited partners. The hospital then sold the net revenue stream from one or more of its outpatient departments (surgery, laboratory, ophthalmology) to the partnership, while still maintaining direct ownership of the department.

The IRS disapproved the joint ventures at issue in GCM 39862 on several grounds. First, the IRS concluded that the physicians in the joint ventures were not sharing in the risks of the joint ventures sufficiently. As the only general partner, the hospital bore responsibility for all of the losses of the joint venture. The physicians, as limited partners, had nothing to lose other than their original investment. Even more importantly, the IRS concluded that the direct benefits flowing to the physician investors were anything but incidental and were in fact the primary reason for setting up the joint ventures. The IRS noted that "giving or selling medical staff physicians a proprietary interest in the net profits of a hospital is indistinguishable from paying dividends on stock." The IRS reasoned that the payment of such dividends is incompatible with the nature of a 501(c)(3) tax-exempt corporation, which is required to be organized to benefit the community and not private individuals. The IRS was also extremely critical of the lack of any corresponding public benefits to the joint venture. There was no expansion of health care resources, no creation of a new provider, no improvement in treatment modalities, and no reduction in the cost of care as a result of the joint venture. The IRS stated that the only public benefit expected from the joint venture – the enhanced financial well-being of the hospital – bore only a tenuous relationship to the hospital's charitable purpose of providing health care to the community.

In light of GCM 39862 and other recent rulings published by the IRS, a hospital organized as 501(c)(3) tax-exempt corporation should follow these general guidelines in structuring the purchase of a physician's

practice or a joint venture with a physician:

- Obtain an independent appraisal of the physician's practice and make sure that all negotiations are at arms' length.
- Make sure that any ongoing compensation paid to the physician after the practice acquisition is reasonable and reflects a competitive rate for the services to be rendered by the physician.
- No more than 20% of the Board of Directors of a tax exempt clinic or foundation may consist of physicians.
- Document the community benefit that will result from the proposed joint venture Benefit to the hospital alone will not be sufficient. Examples of public benefits that often result from a joint venture are lower prices, the availability of new services, better locations, and availability of new equipment.
- If a joint venture is set up as a partnership, make sure that it is set up as a general partnership rather than a limited partnership so that the physicians will share the risk of the venture equally.

SUMMARY

There is a growing trend towards the unification of the practices of physicians under the umbrella of a hospital or group of hospitals. Prior to entering into such relationships, hospitals must test the relationship to be sure that it will not lead to a violation of the anti-kickback statute or, if the hospital is tax-exempt under § 501(c)(3), the prohibition against private inurement under the Internal Revenue Code. These are complex determinations and competent advice should be sought before entering into such relationships.

Footnotes

1 Two other important issues are the effect of physician-hospital alliances on managed care contracts and the impact of the so called Stark II legislation on physician refenals. These two issues are addressed in the outline submitted by Joan C. Ragsdale in conjunction with this outline.

2 For further tiscwsion of the impact of an employer-employee relationship on compliance with the antikickback statute, see discussion at page 9.

3 Respondeat superior is Latin for "Let the master answer". The doctrine of respondeat superior makes an employer vicariously liable for the negligence of its employee, provided that the negligent act was within the scope of the ernployee's employment. See Chamblee v. Johnson-Rast and Nays, 579 So.2d 580 (Ala. 1990).

4 The Alabama Supreme Court has described the theory of "corporate negligence" as follows: "the liability of the hospital is based on its independent negligence in appointing to its medical staff a physician who is incompetent or otherwise unfit, or in failing to properly supervise members of its medical staff. The action is not one in which the hospital is sought to be held vicariously liable for the negligence of a staff physician. The distinction between a hospital's negligence in selecting or supervising its medical staff ("corporate negligence" is the term cornmonly used) and vicarious liability for the negligence of its employees is important because, typically, physicians on the staff of a hospital are considered independent contractors rather than employees. Therefore, vicarious liability does not attach to a hospital for the negligent acts of medical staff members". Humana, 597 So.2d at 669 (guoting 8 Causes of Action 427, 431 (1985)).

5 In order to sustain a claim under an "ostensible agency" theory, a plaintiff must show that the hospital crested an appearance that the physician was acting as an agent of the hospital and that the patient reasonably relied upon that appearance.

6 The severity of these penalties depends on whether the misclassification was intentional or unintentional. Penalties can be mitigated by showing that the worker properly reported and paid income and self-employment taxes.

7 Some of the practices which may violate the anti-kickback statute are as follows:

- Payment of an incentive by the hospital each time a physician refers a patient to the hospital.
- Use of free or significantly discounted office space or equipment in facilities located close to a hospital.
- Provision of free or significantly discounted billing, nursing, or other staff services.
- Free training for a physician's private offfice staff in areas such as management techniques, CPT coding, and laboratory techniques.
- Guarantees that the hospital will supplement a physician's income up to a certain amount.
- Low-interest or interest-free loans or loans that may be "forgiven" if referrals are made to the hospital.
- Coverage in a hospital group health insurance plan at an inappropriately low cost to the physician.
- Payment for services in excess of their fair market value.

8 Many people in the health care industry erroneously believe that a transaction which does not fall within one of the safe harbor provisions is illegal. This is not true. It is the anti-kickback statute itself which defines the scope of prohibited remuneration. The safe harbors simply identify a series of transactions that will not lead to prosecution. As a general rule, the closer a transaction falls to a safe harbor, the less likely it is to lead to prosecution for violation of the anti-kickback statute.

9 Under Alabama law, a non-competition agreement is not enforceable against a physician. See § 8-1-1 Alabama Code (1975, as amended); Salisbury v. Sempk, 565 So.2d 234 (Ala. 1990). Thus, it would not be reasonable to allocate any value to such an asset even in the absence of the Thornton letter.

10 The two detelmination letters were for the Facey Medical Foundation, 2 HLR 429, and the Friendly Hills HealthCare Network, 2 HLR 253.

11 In large part, the difference of opinion between the IRS and HHS can be traced to the different objectives of the IRS and HHS. The IRS is pnmarily concerned with preventing private inurement of a tax-exempt entity's revenue, while the HHS is primarily concerned with preventing improper referrals.

12 To the extent that it is necessary to allocate that portion of the purchase price to the value of the name of the practice and the value of the practice's patient relationships. Allocations of a portion of the purchase price to patient lists, patient records, or noncompete agreements are in advisable.

13 Section 501(c)(3) of the Internal Revenue Code of 1986, as amended.

Dust, Doctors, Donkeys

T. Gerald New, M.D. and Kenneth E. Chandler, M.D.

When Dr. Kenneth Chandler, a general surgeon colleague in Decatur, Alabama, invited me to accompany him to India to help initiate a laparoscopic surgical program at Wanless Hospital, I readily accepted the challenge.

Since the general surgeon entered the field of laparoscopic surgery in 1989 with laparoscopic cholecystectomy, Dr. Chandler has been a pioneer in learning these techniques and subsequently teaching others in the area. My interest in laparoscopy began in training at UAB in 1968 when we were just beginning to use the laparoscope for diagnostic purposes only and over the past two decades it has developed into a keen interest in the field of operative laparoscopy.

As an outgrowth of a mission conference at his local church, Dr. Chandler contacted Dr. Archie Fletcher, a retired missionary surgeon, who expressed the need for help with laparoscopic surgical training at the Wanless Hospital in Miraj, India. This is a 560 bed open air hospital supported by the Presbyterian Mission Board and operated under a nonprofit trust with oversight by a board of directors composed of Indian Christians. This hospital serves as the main teaching facility for the local Government Medical School, a nursing school, an institute of pharmacy and diploma courses for x-ray, laboratory, and medical records technicians.

Miraj Medical Center is composed of the Wanless Hospital, Wanless Chest Hospital, and Richardson Leprosy Center. The first medical clinic was opened in 1894 by Dr. William Wanless, general surgeon and pioneer Presbyterian medical missionary. Today, the Center provides not only basic medical services in medicine, surgery, pediatrics, and obstetrics, but has developed a range of specialties including cobalt therapy for cancer, manufacture of orthopedic appliances and prostheses, burn treatment, plastic surgery, invasive cardiology and cardiac surgery, hemodialysis and kidney transplantation. Miraj Medical Center is the only such medical center for 15 million people within a range of 150 miles. Miraj is a town of about 125,000 people located in southwest India, 286 miles southeast of Bombay. The population is 60% Hindu, 38% Muslim, and 2% Christian. Miraj is know for the manufacture of the Sitar, a stringed musical instrument with the base made from a large gourd.

Dr. Archie Fletcher, who incidentally was a medical classmate of Dr. John Kirklin, was Director of Wanless Hospital for 28 years before retiring in 1978. However, he has maintained a strong interest in the mission and health of the hospital today and is responsible for the travel of many American physicians to Miraj, ensuring the medical staff acquires needed new medical skills. Interestingly, one of the first successful open heart procedures in India was performed at the Wanless Chest Hospital in 1962.

India is a different culture, a different world from Alabama and the medical community as we know it; therefore, its medical establishment was of keen interest to us. Wanless Hospital is the only comprehensive general acute care hospital in the area; however, in the city of Miraj, there are at least 40 private hospitals called "nursing homes." These "nursing homes" are owned by a single physician or surgical group and consist of 20 to 40 beds with operating rooms and diagnostic equipment. These private clinics attract paying patients while all others who cannot afford private care seek medical attention at a government hospital. Wanless Hospital not only serves the indigent patients, but must also compete with these private "nursing homes" for the paying patients in order to survive financially. Therefore, it is essential for Wanless Hospital to offer comparable up to date medical and surgical services.

Our journey began with 19 hours in the air to Bombay and a 10 hour train ride to Miraj where we were met in the early dawn hours of February 7 at the train station by Drs. Bidari, a general surgeon, and Dr. Ranade, a gynecologist. We were taken to Fletcher Hall across the street from Wanless Hospital, our residence for the week. Fletcher Hall is somewhat of a pseudo-western oasis consisting of six double rooms with a private bath and a central lounge and dining area with our own cook, Mohan, who was a whiz with pancakes, toast, and eggs for breakfast and noodles, mystery vegetables, rice and fruit for dinner. We also encountered chicken frequently in its various curried forms. Actually, the food was well prepared and Mohan and his staff were friendly and accommodating.

After a few hours sleep and a pancake breakfast, we attended a daily devotional held in the Chapel adjacent to the hospital. A Christian hospital staff member presents a 15 minute Bible lesson with a hymnal and prayer daily, attended by physicians, nurses, and hospital employees. We were graciously introduced to those attending the service by Dr. Bidari.

Following chapel, we met Dr. Cherian Thomas, Medical Director of Wanless Hospital, who is an internist, but devotes all his time to administrative duties. He was a most gracious host during our stay and later in the week entertained us with an outdoor dinner at his home across from Fletcher Hall, also attended by 30 or more second and third year medical students from the local Government Medical School.

As we entered the hospital proper, most obvious was the uncleanliness of the facility, both outside and especially inside, the operating rooms being no exception. We discussed this with our host surgeons and they too were concerned and aware but admitted resources were lacking to improve the conditions. Basically, the hospital has no maintenance department or organized housekeeping staff. The hospital is open air and visitors and families fill the wards and hallways and many sleep on floor mats beside the patient's bed. With such an arid climate, dust prevails everywhere and is carried into the hospital hallways and patient's wards by foot traffic and the flow of air through the screen windows. There is no air conditioning except in the operating rooms, where it functions intermittently.

To digress for a moment, we were told by Dr. Bidari's wife, also a physician, after arrival that Miraj was famous for the three D's: dust, donkeys and doctors. Dust is certainly omnipresent and donkeys wander the streets unbridled and are humorously considered by the local people as the traffic cops of Miraj. The donkeys have owners, but are allowed to wander the streets and forage for food in the many garbage dump sites along the roadside. Whenever needed to pull a cart or wagon, they are always available – out in the middle of the street.

The hospital has no dietary department, so the patient's family provides food from home or purchased from one of the many small shops lining the street that fronts the hospital. Packaged or freshly prepared, they have almost anything you want to purchase, edible or otherwise – the fast food of India. Obviously, there was little control of the patients' postop diet. The family not only provided the menu, but was very interactive in the patient's treatment. Some family members kept a copy of the medical record at hand and knew the chart by heart and the medical history in more than superficial detail.

Integral to our laparoscopic program was securing a complete laparoscopic instrument setup since the hospital had no laparoscopic equipment except an outdated direct viewing laparoscope with a 150 watt light source. Fortunately, Karl Storz Company dispatched a representative from their Bombay office with a complete set of instruments, videocamera insufflator and light source. Also, US Surgical Corporation donated a large number of disposable endoscopic instruments which proved invaluable during the week.

Mr. Ravi Kanwar, the Storz representative, must have broken a record over the next five days, continuously using his equipment from 8:00 a.m. to 4:00 p.m. daily with very few problems. He deserves a commendation for his untiring work and dedication ensuring the equipment remained operational during our stay.

Tuesday morning, Dr. Chandler and Dr. Bidari, chief of surgery, attempted their first laparoscopic cholecystectomy, but this may have been the worst case of gallbladder disease Dr. Chandler had ever encountered and they soon converted to an open procedure – a temporary disappointment to all. However, during the next three days, they were able to successfully perform four laparoscopic cholecystectomies and one laparoscopic appendectomy with Dr. Bidari successfully performing a complete procedure at the end of the week. Without the benefit of prior training in basic laparoscopic techniques or practice in an animal lab, we were impressed with Dr. Bidari's quick mastery of laparoscopic skills.

As the operative schedule allowed, Dr. Chandler observed other surgical specialists at work and was impressed by their surgical skills under what he considered less than optimal conditions: overhead surgical lighting was of poor intensity and surgical instrumentation was antiquated, sparse, and in worn condition. Major operative procedures observed included a Blaylock-Taussig shunt or Tetrology of Fallot, craniotomy frontal lobectomy for brain tumor, and radical neck dissection for carcinoma of the mouth.

Gynecologic endoscopy began Monday afternoon and was a trial run to determine the operability of the equipment and to familiarize the operating room personnel with the equipment and its function. We were able to perform an extensive pelvic adhesiolysis and drainage of an ovarian cyst. We then followed Tuesday with a laparoscopic assisted hysterectomy, bilateral salpingo-oophorectomy and an anterior repair. This procedure went smoothly considering the OR table was capable of only minimal trendelenburg position, which was a significant handicap. When we initiated the vaginal portion of the hysterectomy, only a small Deavor and Sims retractor were available. There was no weighted speculum, right angle, or medium curved Deavor. I came away impressed how much these well-trained surgeons can accomplish with so little equipment. I resolved I would be more humble back in Decatur General OR in the future.

We performed nine gynecological endoscopic cases; however, most of these involved extensive bilateral

tubal disease. I did not feel that we accomplished much with these cases, as most had undergone previous tuboplasty in private clinics and there was very little salvageable tube to work with. The gynecologists were accustomed to evaluating patients for infertility who had undergone tuboplasty by private physicians not well skilled in the procedure.

Our week was concluded with a summation conference with the general surgeons and gynecologists to review our laparoscopic cases and answer any final questions. We were impressed by their rapid assimilation of laparoscopic techniques and deemed them capable of proceeding with laparoscopic surgery in their hospital. However, with limited financial resources, laparoscopic equipment is not currently available. Our prayer is that money can be secured and equipment purchased before too much time lapses.

Even though we spent most of our days in the operating room, we found time to visit a few points of interest in the community. Most interesting was a visit to a small shop to witness the production of handmade Sitars starting from the Cedar board and gourd to a beautiful stringed musical instrument, a task taking three men about 15 days to complete. An evening ride into the countryside led to a vineyard where grapes were processed into raisins for export to Europe. Dr. Bidari and his wife took us to the sister city of Sangli shopping and the 6 kilometer drive was exciting and terrifying at the same time. I might expound on this last statement because the impression of India most imprinted on my mind was highways - streets - roads. All of India seems to live alongside of the road from daylight till dark and everyone thinks he or she has the "right of way." The roads are teaming with people on foot, bicycles, motor bikes, 3 wheel taxis, ox carts, large commercial trucks, and stray donkeys, all heading down the wrong side of the road in proper British manner and many at breakneck speed. If you've never been there, you cannot imagine the scene, and if you have been there, you can hardly believe what you saw and experienced!

Saturday morning, we began our return trip home with a 35 mile journey from Miraj to Kolhapur airport by automobile. This was one hour of sheer terror – not one for us, but for the people on the highway. The driver of our little white Ambassador car honked the horn almost constantly, narrowly missing objects and persons as he drove 80 kilometers per hour. Dr. Chandler and I were happy to reach Kolhapur airport and even more eager to board the old DC-4 that carried us eventually to Bombay.

Reflections and impressions of this trip are many and varied and some will have a profound influence on us for the rest of our lives. I shall always remember the teeming numbers of people always in the road, the dusty air that pervades Miraj 8 months of the year, the stray donkeys standing in the streets, the vendors across from the hospital peddling their wares, the slums of Bombay with the young women carrying malnourished babies begging for food. Some of these impressions are humorous, but many are depressing – even more so because there is not much I can do to correct these conditions, not directly at least. But more so, I remember the smiling faces of a happy people content with less than the material things we take for granted in our country. Our hopes are that the Christians in India will continue to bring about medical and social changes that will lead to a better life for many of the people of India. Dr. Chandler and I believe our trip was successful and laparoscopic surgery will soon be a reality at Wanless Hospital. We received more than we gave during our week in Miraj and we certainly would like to send the Bombay virus that came home with us back to Bombay ASAP!

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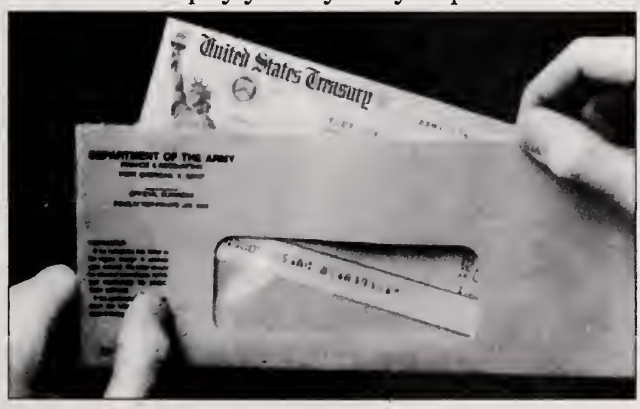
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Eleventh Invitational Scientific Symposium

Saturday, January 28, 1995 - 9 AM to 4 PM
Edna Merle Carraway Convention Center,Birmingham

Purpose of the Program - This program is designed to allow Alabama physicians to share with their colleagues current research efforts and professional concerns. Topics selected will cover a wide range of medical interests.

Program Format - The program will be structured from the papers submitted by Alabama physicians. Registrants will receive copies of all papers.

Paper Selection - Papers will be selected using the following criteria and procedures:

1. The subject matter should be of interest to physicians in a number of specialties. Emphasis should be on medical problems which may be encountered by primary care physicians.
2. This is a program designed for and presented by Alabama physicians, so current local research efforts and professional concerns will be given top consideration.
3. The paper should be one that can be adequately outlined and covered in 20 minutes with additional time for questions. Selectees will be expected to prepare suitable written materials to be used with the presentation for the study and use of attendees.
4. On the final review of papers, members of the MASA Council on Medical Education will select topics from a variety of specialties and physician interests to offer a balanced program of general interest.

"Excellence in Teaching Award" - After the meeting, attendees and the Council on Medical Education will select one presenter for a special teaching award based on teaching skills in presenting information, and quality, clarity and helpfulness of teaching handout materials.

Symposium Timetable

August 15 to November 1, 1994 - Call for abstracts
November 1, 1994 - Final date for abstracts to be received
Early November 1994 - Review of abstracts by the Council on Medical Education and final selection of papers.
November 1994 - January 1995 - Announcement of selections, publicity and promotion of Symposium; Printing of abstract and handouts.
January 28, 1995 - Program presented in Birmingham at Carraway Convention Center

Symposium Topics - to acquaint potential presenters with the kinds of subjects that might be suitable, the speaker and topics at the 1994 Symposium are listed below.
Guy H. Handley, MD - Evaluation and Treatment of Chronic Sinus Complaints; BJ Kraynack, MD & Jaro Mayda, MD - Topical Clonidine Treatment of Postherpetic Neuralgia; Richard Jennelle, MD - Stereoatic Radiosurgery: A Multidisciplinary Non-invasive Surgical Technique; Steven Stokes, MD, et al. - Transperineal Ultrasound Guided Radioactive Seed Implantation as Treatment for Localized Carcinoma of the Prostate in Medically Inoperable Patients; Gregory W. Cotter, MD - Changing Trends in the Treatment of Early Breast Cancer; Ruby Meredith, MD, et al. - Intraperitoneal Radioimmunotherapy for Ovarian Cancer at UAB; Jerry McKnight, MD, et al. - Survey of Alabama Adolescent Sexuality: A Comparison with National Data; Karen Landers, MD - Diagnosis and Treatment of Congenital Facial Deformities; Jonathan S. Pendergrass, MD - Symptomatic Breast Hypertrophy and Breast Reductions Surgery; Keith Parker, MD and S. Hutson Hay, MD - Analysis of Generated Retinal Reflexes; W. Douglas Everett, MD - Colposcopy and LLETZ in a Family Practice Residency Program

Abstracts - abstracts of proposed paper (200-300 words, doubled spaced) should be sent to the Council on Medical Education.

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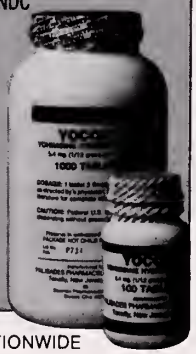
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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THE BOTTOM LINE HAS NO DOLLAR MARK!

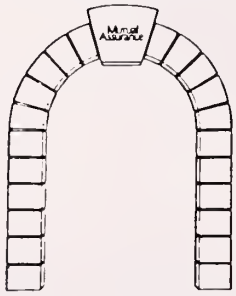
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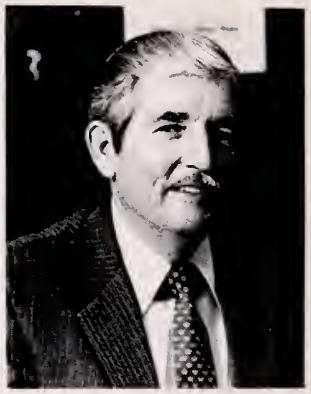
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Whither Reform?

"[Polls] overestimate the amount of information the average citizen has, and underestimate his intelligence."

— Elmo Roper

I believe 1994 will go down in the political science histories of the United States as a year in which public opinion was manipulated to the point that it was simply mangled into a meaningless mess.

All sides of the multi-faceted health care debate prefaced their own point of view with statements typically beginning: "The people of this country ..." followed by "believe... don't believe... want... don't want.... need ... don't need... etc."

There have been literally scores, perhaps hundreds, of polls financed by many, perhaps most, of the 1,162 registered health care reform lobbyists. Uncounted millions were spent on these highly questionable samplings and on resulting propaganda designed to advance every conceivable agenda.

Even the established pollsters, Veteran *Wall Street Journal* Reporter Cynthia Crossen points out in her disturbing new book, *Tainted Truths*, long ago began moving out of objective measurement of public attitudes to take on the highly subjective mission of commercial clients, whose expectations justify the huge fees they pay for such private pollings. Advancing private agendas now provides the bulk of pollsters' income.

While they bristle at the thought that they would dare cook the numbers, there are many ways they can skew methodology to produce findings in support of a client's case. Obviously this was done any number of times by the armies arrayed in Washington in support of the many viewpoints of health care reform.

The hired guns knew perfectly well that the general public had only the most superficial grasp of this, probably the most complex subject ever debated in this country. Exploiting that ignorance, it was child's play to get the results the customer wanted.

Perhaps at the suggestion of Ms. Crossen, who has long demonstrated a healthy cynicism toward what is presented as public attitudes, tendentious statistics, and "established truths," The *Wall Street Journal*/NBC poll some months ago first reported the results of a poll showing precipitous decline in public support for the "Clinton health care reform plan."

Then, to check on the validity of these findings, the pollsters removed Clinton's name from the question and substituted for it various cardinal elements of the President's plan and asked for voter sentiment. You have probably already guessed that this blind poll produced broad and deep public support for exactly the same plan that had been so poorly received when identified as the President's.

What does this prove? I can only guess. First of all, the two findings would seem to suggest that Mr. Clinton has a severe credibility problem and his support may have become a kiss of death. But the paired studies also suggest that the general public does not sufficiently understand enough of the ramifications and permutations of any reform proposal to offer an informed opinion on the subject.

Otherwise, respondents would have detected that the second question was the same as the first. The clients who paid for this did not have a hidden agenda. They were simply interested in establishing the degree of public comprehension and the extent to which understanding is colored by prejudice. In my own view, this case casts doubt on all polls purporting to show what the public thinks about complex, involute subjects.

An academic expert on polling cited by *Tainted*

Truths said there are two fairly simple tests anyone can apply to purported public attitudes. (1) If you see a poll result that seems preposterous to you, it is very likely invalid, for whatever reason. (2) Before you embrace any poll, find out who paid for it. An example cited in Tainted Truths is a poll on the penny, a coin many believe obsolete. The polls found that almost two-thirds of the American people want to keep the penny.

Now that may be valid (even though I share the sentiment that supports abandoning the penny). But are you reassured by learning that the poll was financed by the zinc industry, which earns big bucks supplying metal for penny-minting, and profits enormously by the fact that untold megatons of pennies lie out of circulation in desk drawers, fruit jars and even in garbage cans?

There are many ways to manipulate the results sought. One of them is by "position bias." The question the client wants answered in a manner favorable to his agenda is placed in the questionnaire at such a position as to be influenced by the context of preceding questions. Here is an example of how that might work in practice:

During the height of the cold war, when Americans were still highly suspicious of everything associated with the Soviet Union, respondents were asked whether writers and correspondents of any and all Soviet publications should be allowed to travel anywhere in this country and send back whatever they choose without restraint of any kind.

The negatives prevailed; Americans didn't see any reason to facilitate Soviet propaganda. In a second poll, the same question was asked, but preceded by this one: Should American reporters and film crews be allowed free and unfettered access to every area in the Soviet Union and to send back any reports they choose, without restraint from Soviet authorities? Following that was the original question about Soviet journalists in this country.

You would not be surprised, I am sure, to learn that by asking the question paired in such fashion respondents proved to be much more tolerant of Soviet journalists roaming America. Americans' traditional belief that turnabout is fair play must have played a role.

The point, however, is that answers can be greatly influenced by context, and dozens of other factors. They can also be influenced by what is called "file drawer bias." A client who doesn't like the poll results, simply files them away as confidential. He paid for the poll and he can jolly well conceal the results if he likes.

Question complexity creates another bias. When Americans were asked whether or not they believed it possible that the holocaust never occurred, the double negative so confused respondents that the results were that an unbelievably small percentage of Americans actually believed Hitler had exterminated 6 million Jews, despite overwhelming proof and documentation.

But when the question was clarified, only a small percentage — no larger than the lunatic fringe on almost any question of this kind — actually doubted Hitler's holocaust. Had it not been for the grotesque size of doubters in the original poll, the result might have stood.

Recent in-depth studies have also shown that people tend to lie when the question involves political correctness or other attitudes which might call into question their patriotism or civic virtue.

A major insulation against poll manipulation, however, is that there is widespread public disenchantment with polling. In the health care reform debate, for example, when adversaries in Congress quote diametrically opposing studies of what they say Americans want and are prepared to pay for, who among us is equipped to examine the methodology of the respective polls and thus determine which is reliable and which suspect? We simply doubt all of them.

My thesis is that this is a heck of a way to run the country — citing poll results. Leaders are supposed to lead — to shape public opinion, not just weathervane to every point of the compass as the wind changes.

Some observers have made much of the fact that the public changed its tune when it began to suspect that health care reform would not guarantee a free lunch. That appears to be true. But it is also true that most of the other supplicants in the reform parade were just as greedy. Business and industry expected a lot more than just the elimination of cost-shifting — they wanted relief from the burden of supporting their early retirees, and Clinton recklessly promised them that.

In fact, just about every lobbyist in Washington was charged with getting some special privilege, benefit, dispensation, or hand-out for those who hired him. Small businesses have generated a continuous, raucous din of opposition to any suggestion that they do the right thing by their employees. So shrill has been their opposition that it seems clear that their real objective is to have the rest of the country pay their premiums, through subsidy or however.

These past few months, Washington has been a haven for advocates for various deadbeat groups. The mutual sacrifice that characterized the origins of the reform movement died young, succeeded by gimme-gimme. When everybody is intent on feathering his or her nest, the result is no nest.

I suggest that Oliver Wendell Holmes was right when he said that the only public opinion that counts is judgment that comes "out of experience and under the spur of responsibility." And neither is easily gained in weighing alternatives involving $1 trillion a year, one dollar in every seven that we produce as a people.

The public debate on health care reform has been neither responsible nor informed. I am beginning to doubt that a debate on this plane is possible, even under the best of circumstances. And that may augur ill for the future. It may mean that the most accomplished demagogue wins.

PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

The Bottom Line Has No Dollar Mark

Following is the text of Dr. Hall's remarks to 1994 graduates of the UAB School of Medicine. – Ed.

You are entering the noble profession of medicine in an age when too many Americans know the price of everything and the value of nothing.

Medicine itself is threatened, from within and from without, by this same rampant materialism and spiritual nihilism.

Just two generations ago, your professional forebears gave the very best that was in them even though many of their patients could not pay. It was the great depression; few people had any money.

Physicians cheerfully accepted barter — a chicken or a ham for services rendered. Or nothing but gratitude.

During World War II that followed, health insurance proliferated as a a wartime substitute for wage increases, which were suppressed by emergency powers.

Although scarcely noticed during the war, the monetarization of health care had begun. Two decades later, this process was given another push by the passage of Medicaid and Medicare.

In another 25 years came a convoluted system for determining the relative value of physician services. At this very moment, other computer programmers are writing software that will translate every disease process and convert every service you perform into bits and bytes of data. They are meticulously quantifying the art and science of medicine into work units and dollars, out to the fourth significant figure, if the payer so orders.

Since most of you will enter practice with a substantial debt for your training, it will be tempting to succumb to this monetarization as your personal standard of care. If you do, you will come to think of your patients as dollar marks. By that route, you will assuredly become a successful business man or woman. But you will never become what you had set your cap to being — a consummate physician.

Thirty-seven years ago, in a speech to the professional and graduate schools at Emory, Federal Judge Elbert Tuttle saw early signs of the decay of values so evident in 1994.

What he said in 1957 is even more relevant today. His advice was timeless. I am quoting from his speech:

"Do not set a price on yourself. Do not measure out your professional services on an apothecary's scale and say 'only this for so much.' Do not debase yourself by equating your souls to what they will bring in the market. Do not be a miser, hoarding your talents and abilities and knowledge ... Rather, be reckless and spendthrift, pouring out your talent to all to whom it can be of service ...

"Throw it away; waste it and in the spending be of service. Do not keep a watchful eye lest you give away a little bit of what you might have sold ... Like love, talent is useful only in its expenditure and it is never exhausted.

"Set what price you must upon your service. Never confuse the performance, which is great, with the compensation, be it money, power or fame, which is trivial."

I would add to judge Tuttle's timeless counsel only this thought:

Let the bean counters worry about relative values and bottom lines. Concern yourself with top-of-the-line care and absolute values. Think not how little you can give each patient but how much. Call yourself to account frequently: "Am I practicing a trade or a profession?" Think often about the difference. Cultivate the critical attitude of self-accountability. Any true professional must satisfy himself first.

If you set your course now to do that, you will never make the list of the wealthiest men and women in the land. But you will nevertheless grow very, very rich — rich in the immense and unparalleled fulfillment that comes from a lifetime of conscientious, unstinting service in the quiet art of medicine.

Have a good life. Thank you.



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Prescribing For Patients In Recovery From Addiction

Physicians Recovery Network (PRN)

Individuals in recovery from alcohol and drug addiction must at all times be mindful that relapse can be triggered by mood-altering drugs other than the primary drug of choice. Physicians caring for patients in recovery should be vigilant when prescribing for them. Recovering physicians especially should be on the alert that self-medication with opiates or sedative drugs, such as the benzodiazepines, is very likely to promote relapse. Generally, over the counter preparations should be closely examined for the presence of mood altering constituents. There are exceptions which dictate the use of these drugs, such as illness, surgery or accident. Using such drugs should then be under the care of a physician knowledgeable in the addiction process.

Hidden sources of alcohol, such as those found in elixirs, tonics, and vitamin preparations are notorious offenders. Antihistamines, cold preparations, and sinus medications often trigger the recurrence of the addictive process. Even physicians, dentists, pharmacists, and nurses may not be aware that many prescription drugs can reactivate the chemical abuse process.

The bottom line is that the patient and his physician must assume shared responsibility for what medication the recovering patient may use. The following safety rules should be remembered:

1) Carefully read the labels on all medications and/or substances which you put into your body.

2) Be alert to cross-addiction and the rekindling dangers. If in doubt, discuss with a health professional trained in addiction medicine.

3) Never self-medicate or self-prescribe, even antibiotics. Self-medicating may reactivate denial in the disease process.

The following survey, although not entirely inclusive, offers a guide to a cross addiction drug alert list.[1]

The Cross Addiction Drug Alert List

DRUG TYPE	MOOD ALTERING INGREDIENT	DON'T TAKE	DO TAKE
PAIN RELIEF	caffeine	Anacin® Trigesic® Vanquish® Excedrin® Excedrin PM® Cope® Midol® BC powder®	Aspirin Tylenol® Advil® Nuprin® Motrin IB®
	PRESCRIPTION (R)		
	codeine	Fiorinal #3® Phenaphen #1,2,3,4® Empirin #1,2,3,4® Tylenol #1,2,3,4®	Motrin®, Naprosyn® Feldene®, Anaprox® Clinoril®, Orudis® Tolectin®
	oxycodone	Percodan®, Percocet® Tylox®	Ansaid®, Voltaren® Dolobid®, Indocin®
	hydrocodone	Hycodan®, Vicodin® Hydrocet®	
	meperidine	Demerol®	
	hydromorphone	Dilaudid®	
	morphine	MS Contin®	
	pentazocine	Talwin®	
	propoxyphene	Darvon®, Darvocet®	

The Cross Addiction Drug Alert List

DRUG TYPE	MOOD ALTERING INGREDIENT	DON'T TAKE	DO TAKE
COUGH AND COLD	diphenhydramine	Benadryl®, Benylin®	Naldecon Senior EX®
	chlorpheniramine	Teldrin®	DM Naldecon Senior DX®
	pseudoephedrine	Sudafed®, Sine-Aid®	DM Delsym®
		TheraFlu®, Drixoral®	DM Mediquell®
	phenylpropanolamine/ chlorpheniramine	Actifed®, CoAdvil®	DM Vicks Children's Cough®
		Allerest®, Contac®	DM St. Joseph Cough Suppressant®
		Comtrex®	Orthoxicol®
		Triaminic®	
		Coricidin®, Alka-Seltzer Plus®	
	phenylephrine alcohol	Pyrroxate®, Ornade®	
		Dristan®, Dihistine®	
		Robitussin®	
		Contac Nighttime®	
		Formula 44®	
		Naldecon®	
		Dimetapp®, Dimetane®	
	brompheniramine		
	PRESCRIPTION (℞)	Bromfed®, Isoclor®	Seldane®
		Robitussin AC & DAC®	Hismanal®
		Tussinex®	
		terpin hydrate	
		Dimetane DC & DX®	
		Tavist®	
NASAL DECONGESTANT SPRAYS	phenylephrine	Neo-Synephrine®	Ayr Saline®
		Sinex®, Dristan®	Humist®
			NaSal®
			Ocean®
	oxymetazoline	Afrin®	
	phenylpropanolamine/ chlorpheniramine	Sinarest®, Allerest®	
	xylometazoline	Otrivin®	
	PRESCRIPTION (℞)		Nasalcrom®
MOUTHWASH AND MOUTHCARE	alcohol	Cepacol®, Scope®	Chloraseptic®
		Listerine®, Lavoris®	Gly-Oxide®
		Listermint®, ACT®	Fluorigard®
		Viadent®	Isordettes Sore Throat Spray®
		Sucrets Spray and Mouthwash®	Sucrets Lozenges®
			Halls Lozenges®
			Nice Lozenges®
			OxyFresh Mouthwash®
	PRESCRIPTION (℞)		Peridex®
DIARRHEA	alcohol	Donnagel® (liquid)	Kaopectate®
		Immodium AD® (liquid)	Diarrest®, Devrom®)
		Parapectolin®	Lactinex®, Immodium®
			Peto-Bismol®
	PRESCRIPTION (℞)		
	atropine/scopolamine	Donnatal®	
	phenobarbital/atrophine	Donnagel PG®	
	diphenoxylate/atropine	Lomotil®	

DRUG TYPE	MOOD ALTERING INGREDIENT	DON'T TAKE	DO TAKE
NAUSEA AND VOMITING	dimenhydrinate cyclizine meclizine	Dramamine®, Triptone® Marezine® Bonine®	Emetrol® Pepto-Bismol®
	PRESCRIPTION (℞) scopolamine	Transderm Scop®	Tigan® Reglan®
	promethazine prochlorperazine	Phenergan® Compazine®	
DIET AIDS/ STIMULANTS	phenylpropanolamine	Dexatrim®, Acutrim® Control®, Appedrine® Grapefruit Diet Plan®	Slim Fast®, Dynatrim® Diet Ayds®, Diet Aid® Slender®, Metamucil®
	caffeine	NoDoz®, Quick Pep® Vivarin® Coffee, Tea, Soft Drinks	Decaffeinated Drinks (most contain less than 3% caffeine)
	nicotine	Tobacco Products	
	PRESCRIPTION (℞) amphetamine/derivatives	Ritalin®, Desoxyn® Ionamin®, Biphetamine® Fastin®, Dexedrine® Preludin®, Tenuate® Bontril® Cylert®	
	pemoline		
SEDATIVES	diphenhydramine	Compoz®, Excedrin PM® Nytol®, Sleep-Eze 3® Sominex®	Chamomile tea Warm milk
	pyrilamine doxylamine	Somnicaps® Unixom®	
	PRESCRIPTION (℞) benzodiazepines	Halcion®, Ativan®, Serax® Restoril®, Dalmane® Tranxene®, Valium® Centrax® Xanax®, Librium®	
	chloral hydrate ethchlorvynol barbiturates	Notec® Placidyl® Seconal®, Tuinal® Fiorinal®, Nembutal® Amytal®, Phenobarbital®	
	glutethimide methyprylon meprobamate	Doriden® Noludar® Equanil®, Miltown®	

The cross addiction drug alert list is not intended to be absolutely complete. However, the more commonly encountered drugs which need to be avoided are listed. To answer further questions members of the Alabama Impaired Physicians Committee and the Medical Director of the Physicians Recovery Network are available by calling (205) 261-2044 or (205) 263-6441.

1. Talbott, G.D., et al: The Cross Addiction Drug List; Copyright 1991 by Talbott-Marsh Recovery Campus, Atlanta, Georgia. Reprinted with permission.

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Dr. Secrest received his B.A. degree from the University of Mississippi, and earned his medical degree from the University of Mississippi School of Medicine. He completed his internship and residency in General Surgery at Baylor University Medical Center in Dallas, Texas; served a residency in Urology at the University Medical Center in Jackson, Mississippi; and a fellowship in Adult and Pediatric Reconstructive Urology at Eastern Virginia graduate school of Medicine in Norfolk, Virginia.



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The Impaired Female Physician

*G.L. Summer, M.D.**
N. Jane Roark, M.D.†
*Laura L. McClintock, D.O.***

The number of female physicians has increased in recent years, with women now making up a significant percentage of each class entering medical school. Upon graduation the young doctor, male or female, is often placed on a pedestal, expected to be perfect in social, personal and professional endeavors. The same compulsiveness that contributed to success in educational endeavors thus sets the stage for conflicts for the young physician who begins the lifelong process of juggling relationships or marriage, potential or actual parenthood, and medicine. In reality it is not unusual for female physicians to suffer from burn-out syndromes while trying to balance family responsibilities and medical career demands. Women physicians may even find that because they are physicians, their husbands expect them not to have the emotional needs that other women do.[1] Women physicians additionally bear the burden of social isolation since support and mentoring are less available to female physicians making important personal and professional transitions. Even if such support is available, physicians in general are less likely to express distress or ask for help. In spite of this, most are successful, though some fail. Others fall victim to the disease process of alcoholism or chemical dependency.

The AMA has reported that 10-15% of physicians will become dependent on drugs/alcohol at some point in their professional careers. Treatment centers providing chemical dependency treatment designed for health professionals report smaller numbers of female than male patients.[2] In the past three years, the Physicians Recovery Network (PRN) has assisted comparatively fewer numbers of female physicians than male physicians. As more female physicians enter practice in Alabama and a better understanding of the disease concept evolves, more will need the advocacy efforts of PRN and physician colleagues. The intense social stigma applied to chemically dependent physicians, especially women, tends to keep them in hiding. In the later stages of the illness she takes drugs alone, drinks alcohol alone, and becomes progressively more isolated. Enormous amounts of guilt and shame play a dominant role in the disease process. Like her male counterpart, she may appear to be a well-dressed, socially and professionally competent physician who has it all together, but in reality be actively addicted. Her family life may be in shambles long before the impairment affects her professional competence; thus, the disease progresses to an advanced state before help is offered.

Alcohol and other drug dependencies express themselves differently in male and female bodies.[3] Physical differences exist which may explain how a woman will react more intensely to a dose of alcohol and be less able than a man to predict the effects of any given amount of alcohol she might consume. Lipid-soluble substances such as benzodiazepines and some barbiturates have long half lives in women.[4] The disease itself proceeds faster in women than in men for reasons that are unclear.

Women physicians who present with physical problems may be masking a serious addiction as the following sad tale demonstrates:

This middle-aged Alabama physician had a long history of incapacitating headaches which had been evaluated by several physicians. She had used various mood-altering chemicals and made multiple visits to several emergency rooms to obtain intravenous morphine and other opiates. She had been admitted to the hospital on several occasions for headache and opiate sedation and had left against medical advice. Her personal and professional life was in disarray as reflected in multiple marriages and divorce and changing practice locations. Poor coping defense mechanisms were evident as exhibited by rationalization, justifying events, and blaming others. At the time of intervention, she was not employed. Her evaluation revealed a diagnosis of chemical dependency. She was not compliant to the recommendations of the treatment provider. Her current status is unknown.

Physicians have better treatment outcomes than the general population. Family support, witnessed urine drug screens, participation in Alcoholics Anonymous and other recovery programs, favor an excellent prognosis. Close monitoring by a full-time impaired physicians advocacy program contributes to a better prognosis with overall success rates reported between 83.8% and 97.5%.[5,6,7] Although these reports do not differentiate between male and female physicians, there is no indication that there is a gender difference in the prognosis.

The dilemma of the isolated addicted female physician, overwhelmed by the demands of a medical practice, separated from support systems, and unable to

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**Mobile Psychiatrist



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reach out for help is clearly illustrated as this physician, who remains anonymous, tells her own story:

My license to practice medicine in Alabama was revoked in October of 1991. I was one of the best physicians you could hope to meet. I was knowledgeable, caring, conscientious, respected by staff and loved by patients. For the most part, I dealt with the daily problems in practice like a skillful artisan.

There were, however, a few problems that no one knew about except me. Not taking care of "me" had become a major problem. It was a problem that I had been introduced to in 1987 when I had entered the Betty Ford Center for addiction to Demerol. Back then, I was still naive enough to think that there was no such thing as cross-addiction. In AA it is said that there are addictions to people, places, and things. I remember leaving treatment thinking that I would never again touch Demerol, but should a special occasion come up, just a simple drink might be nice. After all, alcohol had really not been my problem. I actually believed that attending a few AA meetings and "Just Saying No" would solve any future problems. To say that I was wrong would be an understatement.

Up until 1987 I had been one more All-American success story. I was privileged to attend the best of schools, having become a leader in prep school and an achiever in college. After medical school I opted for Internal Medicine and even served as Chief Resident during my final year of training. Non-stop I opened a private practice in one of California's nicer areas. I did not realize that the roller coaster ride was just beginning.

It was two years of intensity beyond belief or expectations. Previously I had formed images of slowly building a practice and that life would be pretty sweet. I suppose in part it was because I was a woman, and there was such a need that when I opened my door, the patients came in numbers. Soon, my little BMW was the first and last to be sitting in the parking lot. The balance of successful living had somehow escaped me and I found myself living just to work. Though it consumed me, it was not the work per se that was the problem. It was the emptiness at the end of the day, that came from giving so many pieces of myself away. This was done without making the time and effort to replenish the "warehouse of my soul." I did not take time to rest when I was tired, or eat when I was hungry. I suppressed anger (I had no time for that!) and failed to ask for help in my personal life, even though I had no such problem at work. When I reviewed my schedule for the day or week to come, I wouldn't even notice that there were no blocks of time for me. You could say that this was an accident waiting to happen.

One morning I was awakened by a pounding earache with a headache to match. I had ignored sinus symptoms for a few days and the symptoms had returned with a vengeance, no longer to be denied. I made it over to the ENT doctor who gave me some antibiotics and pain medication samples, telling me to call if there was no improvement within 24 hours. The pain seemed to worsen before it improved with no relief from the samples. I called him back the next morning and he asked if I had any "injectables" in my office. Upon searching I found some unopened, two year old Demerol. I reluctantly gave myself an injection and as you might guess, the relief was miraculous. The idea of possible addiction never entered my mind, nor I'm sure the mind of the nice ENT man who was just trying to help me out. When I walked to the parking lot that afternoon, I didn't mind that my car was one of the last remaining. I felt eased and experienced a sense of what I would call a "numbed elation." The next day at work I debated whether to use the Demerol just "one last time, " though by then the antibiotics were actually doing the work. I waited until the patients and staff had left, until my call coverage was official and then gave myself another injection.

The second time seemed even better than the first, and in my mind I remember thinking "this could be a problem," and yet I didn't care. I needed a vacation and since I didn't have time for one, this was surely the "next best thing."

As any sensible person might anticipate, it didn't take long before I was missing appointments, canceling meetings, not answering my phone at home, ignoring bills and isolating from family and friends. After a number of months my self-esteem had hit an alltime low, and by luck I happened across a phone number in a medical association journal. It had been established for physicians who might have questions about possible addiction / alcohol problems. The suggestion at the other end led me to a meeting for physicians. It truly was anonymous and the other doctors really weren't interested in reporting me to anyone. Their stories were strikingly similar and I left there in amazement. When you are relatively naive about something and are carrying around a "secret," the shame you feel can be extraordinary. That is until you discover that you are not alone and are one of many. These physicians were accomplished and successful. They weren't losers – not even one of them. To this day, I win occasionally hear on TV or read in the papers about one of their accomplishments and I am left smiling, being even more convinced that recovery works.

Within a week or so I had entered the Betty Ford Center. It was a powerful experience and I met many friends there. I left at the end of 28 days thinking I had the sobriety "thing" down cold. This was through no fault of my counselors however, since I could only see what I was willing to see. It was similar to college days when you studied like crazy thinking you knew "the stuff" only to leave the exam with the feeling like you surely must have studied the wrong chapters!

After a relatively long period of sobriety, I decided to move to Alabama. Generations of family have lived here, and so not only were there "roots" but through many visits over the years, I had concluded that life seemed simpler and more peaceful. I sold my practice

and packed my boxes. Little did I consider that in the move also would come all the unresolved internal conflicts, past and present. My original problem of not taking care of myself still surfaced on a frequent basis. It was hard to get away from being a "people pleaser," and I rarely said "no" when asked to help out with a problem. After all, problem solving was what I did best. The paradox was, of course, that in solving other people's problems, I created one for myself.

It is a well-known truth that you must locate a "primary" in treating a patient's cancer... cut a weed to the ground without removing the roots and it will come back. And so this too is what happened with me.

My country practice was growing and life was sweet. Unfortunately, I was still not taking care of myself: My relapse in 1991 began with alcohol. Something that I could take or leave in previous times turned into a new preoccupation. This served to weaken my resistance, and my judgement so that it was not long before I began using Demerol again. The discovery of this came while I was hospitalized for pneumonia. Inadvertently the Demerol was spotted by a nurse when it rolled out of my purse. Needless to say, a bad scene followed. I was ordered from the hospital, and my doctor refused to treat me any longer. Within days I received a handful of certified letters; the medical board, the local hospital, the medical staff, the DEA, the malpractice insurer and a crook of a small town attorney offering his "help."

It took a few months to recover from the bilateral pneumonia and decide that the continued drinking needed to stop. My choices were to continue in the downward spiral, to kill myself or to get some help. Hard as it was, I chose the latter and within the week was a patient at Hazelden, the Minnesota facility which is the grandfather of them all. While I was there, my license to practice medicine was officially revoked without the benefit of my presence or that of an attorney at the hearing With the 20/20 vision of hindsight, I doubt that it would have made much of a difference if had been represented at the hearing, but the timing seemed bad. It was like kicking a dog that was already down. But that's they way it happened, and so with help, I dealt with it.

I deliberately took the next 2 1/2 years off. This time, I was determined to take the time. I chose not to engage in what I had perceived would be the fight to win my license back. I didn't have another fight left in me. What exactly I did is too detailed for this story, but I will say that I allowed myself grieving time and spent many days soul-searching and getting in touch with a Higher Power. I was very fortunate to have the financial support of my family. And though they did not understand, they didn't give me a hard time about not working. For this, I will always be grateful. I defined the trigger points for me in relapse and specifically what I needed to do in order to take care of myself. It seems so simple for those who just seem to know how to do this naturally, but for me this was quite a mountain to climb. With the help of a therapist, I also have begun to work on my past and the lessons to be taken from the memories and experiences... to finally work through tragedy that I had long ago mininized or forgotten. In short, I began the healing process of injuries which had caused pain so severe that it seemed only Demerol could help.

I reapplied for my Alabama license and was actually surprised how uncomplicated and painless this proved to be. I know a great deal of credit must go to the Physicians Recovery Network (PRN) in Alabama. PRN did not exist when I had my 'problem" in 1991. There did not seem to be a good sense of what this type of problem was all about and then how to evaluate the best way to help a physician in order that they might return to practice. Things have changed and I find this very hopeful. Through continued treatment and monitoring, safeguards are now in place. I consider them all to be logical, reasonable, and even helpful.

Each of us has demons which we must live with and conquer. But we do not have to be alone in this battle. It is the brave man or woman who asks for help, not the coward. My attitude has changed and so, therefore, has my life. The road to recovery is not always easy, but compared to the alternative, it is definitely more honest and healthy, at times even being joyous.

I lost a great deal: time, self-respect, financial stability, my profession, my health, and the respect of others. In turn "they" lost a gifted physician and a friend. I am most grateful that today the things that really are important have been returned to me. I have a ways to go, but I now can say that I look forward to the journey.

"The danger is not lest the soul should doubt whether there is any bread, but lest by a lie, it should persuade itself that it is not hungry." – Simone Weil (Waiting on God)

This physician's story illustrates that recovery takes time. A reduced stress time factor is needed to re-pattern behavior and learn new, non-chemical coping skills. Open and honest interaction with peers who share the same disease serves to bring about the initial resolution of guilt and shame. Adjustment to a changing self-image and lifestyle comes slowly, but is a necessary part of recovery. She is currently involved with the advocacy efforts from PRN and is a valuable physician resource in Alabama.[8]

Chemical dependency does not discriminate against gender, race, age, nor social status. Physicians need to be aware that addiction spares no one. Sick doctors rarely reach out for help on their own initiative. It is not realistic to wait until behavioral aspects of the disease impact upon the medical practice or patient injury occurs. Rarely will a physician be observed self-medicating or drinking on the job. What will be noted are family problems, changing jobs, poor coping mechanisms, and progressive isolation personally and professionally. When this occurs we can ask

ourselves, "How can I help?" The PRN makes available female physicians to assist their colleagues. A confidential call to 205-263-6441 or 261-2044 or 1-800-239-6272 will begin the helping process.

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*James A. Pittman, Jr., M.D.**

CONGRATULATIONS! Congratulations first on your completion of a demanding course of study in which you have learned, mastered I hope, the knowledge, attitudes, and skills necessary to be a good medical technologist. *Knowledge, Attitudes and Skills (KAS)* these are the three things on which your success or failure in the future will depend. You cannot afford to be deficient in any of the three.

If you lack the knowledge, you may have a great attitude and superb manual dexterity, but you're dead in the water. You cannot move forward without solid, reliable and ever expanding knowledge of your work. In fact, you cannot even do your job today. I say "ever expanding" because medicine is always looking for better, more accurate, cheaper, simpler, quicker, less risky, less painful ways to do things. Even if the NIH budget and commercial research budgets do shrink, there will still be new methods, new reagents, new instruments coming along, and you must *read* and *study* and *meet frequently with colleagues* to keep abreast of these new developments. In a few years, you may discover that the chemistry of a new chemiluminescence technique is actually a lot more interestina than the latest soap opera – even though your kids don't understand that yet. As Alice in Wonderland discovered years ago, you have to run hard just to stay in place. *The person who READS is the person who LEADS!*

If you have the knowledge and skills but have a lousy, uncooperative, non-communicative attitude; or an arrogant attitude that says, "I don't have time for you," – if you have that attitude, you won't last long in a good lab. The good lab tech answers the phone or inquiry promptly, is polite, *listens* very hard and tries hard to *understand* what the clinician or boss of the lab is asking, then tries to provide the necessary information as quickly and accurately and pleasantly as possible. He or she looks for ways to be helpful, despite the always excessive workload and time shortages. It is an attitude that gives top priority to *service*, because that's what we're in: a *service "industry."*

Of course, the *skills* you have now and will develop further in the future are at the heart of your work, skills at understanding and operating some of the most sophisticated machines in medicine – the multichannel automated chemical analyzers, instruments for immunologic assays using multiple antibodies, chemiluminescence assays (some developed right here in Alabama at UAB), morphological examinations of all sorts – preparations for autopsy examinations, surgical specimens, cytological examinations on which some patient's *life* will depend – as in the detection of malignant cells in a pap smear – or on which treatment will depend, as with clue cells on a cervical smear, or chromosmal abnormalities in white blood cells indicative of a particular kind of leukemia, or the identification of a particular bacterium or virus as the cause of an illness and distress in a patient. Or perhaps you will be doing EKGs or EEGs and evaluating the electrical activities of some patient's body.

And the *frontiers* will always be there – the *challenges* to find better ways, ways to advance medical understanding – newer and better FACS machines (fluorescence activated cell sorters) or improved amino acid analyzers to advance immunology and clinical chemistry, diagnostic molecular biology – DNA sequenators for genetic analyses (for example in the O.J. Simpson trial), linked LC-MS and GC-MS instruments (liquid chromatography-mass spectroscopy and gas chromatography-mass spectroscopy), hematology/coagulation labs, "transfusion medicine" and blood banking, and all the rest.

I talked with Drs. C. Bruce Alexander and John A. Smith of UAB Pathology about this convocation, and they urged me to stimulate you to work on your *computer skills*. Computers are important communication instruments already and will be even more important in the future. The more you can know and understand about how they work, and the more you can make them do your work, the smoother things will go. There will be satellite communications, communication networks, networks of POLs (Physician Office Labs), communications with nursing homes and home test-

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ing with kits (perhaps by hand-held computers), and lots more. Maybe, after working a few years out in the real world, you should get a Master's in *computer science!*

One of the problems in life is that we *lose the wonder of it all.* As kids we stand in awe of the wonders and mysteries of medicine and medical technology. It all seems so *romantic* and *exciting.* Then, we work hard, get through school, then through med tech school, then get a job, have to be there on time, have to work hard all day and maybe stay overtime without extra pay, have to work with other people who are difficult or dumb or just unhelpful. And we begin to think, "What a bore all this is. What a burden and bother. I wish I could spend more time relaxing, maybe at the movies, with my friends" (or husband, wife, or kids). At that point we will have *lost the wonder, lost the spirit* which made it interesting.

Don't Let That Happen! Once in a while stop to reflect on how great it is – what you are doing.

Homeostasis, that's one of the keys to our job. "Homeostasis" is a word coined by Walter B. Cannon, M.D., the famous physiologist at Harvard at the turn of this century who first used radio-opaque material to outline the gastrointestinal tract – first a button in a goose, then bismuth, then a barium suspension in human beings. Well, Dr. Cannon also developed some of our modern concepts of *Constancy of the body's internal environment*, or *Homeostasis,* and *regulation of body components*, like the chemicals in our blood. He called this regulation *"homeostasis."* This regulation keeps the internal environment of the body constant so the body can function normally – the blood pH must remain around 7.4, the serum sodium about 145 milliequivalents per liter, potassium about 4.0, bicarbonate 28, blood urea nitrogen 18, creatinine 1.0, and on and on. As you look across the laboratory reports in the future, each time notice how *narrow are the limits* within which the body keeps these things we can measure – not only the ones I just mentioned (serum sodium and the like) — there are more than a hundred routinely measured in labs in the U.S. today, and thousands more in special analyses. And they are kept within narrow limits of normal. This *constancy of the internal environment – Homeostasis* – is an amazing thing, and your work will largely be to check whether the body of a particular patient is doing this. Every time you look at a lab sheet, with the patient's values printed near the *normal range*, remember, when you see that normal range: *Homeostasis.* When that's out of kilter, the patient is sick.

Second, congratulations on entering an ancient and

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honorable field. I would say that *chemistry* is at the heart of your work, though obviously *immunology* is also critical, and physics, anatomy, microbiology, immunology, and many other disciplines are also important. But *chemistry* is the basic discipline.[1]

I am old enough to remember some of the *history* of the developments from the 1940s and '50s. I remember how I measured oxygen consumption of bacteria or tissues with a Warburg apparatus in the 1940s. Now you can find Warburg vessels only in museums! Or how at the NIH in the '50s I measured blood levels of various drugs using the Bratton-Marshall diazotization reagent, then estimated the quantities by the intensity of color of the solution in a Coleman Junior or Beckman DU spectrophotometer. Or how I attempted to measure serum and fecal calcium levels colorimetrically. I knew Berson and Yalow *before* they developed the radioimmunoassay, for which Ros Yalow received the 1977 Nobel Prize.[2] Their method is the foundation of those used for the majority of hormone determinations these days, only now being replaced by the conceptually similar chemiluminescent assays. It has been remarkable to watch these developments.

Before I close I want to tell one story and make two more points.

The story illustrates why I, as a clinical endocrinologist, hold chemical determinations in very high regard. (I used to actually run a lab, the old endocrinology lab at UAB, before these modern times.)

One dark and stormy night (and it *was* dark and stormy, like recent weeks here, with tornadoes, floods and all) – One dark and stormy night I traveled to Tuscaloosa for a clinical conference. At the conference one of the state's and nation's leading internists[3] presented me with a case of a patient suffering from terrible fatigue and feelings of exhaustion, marked darkening of the skin, anorexia and loss of appetite, and recently nausea and diarrhea, with a very low blood pressure. The physician did obtain blood electrolytes, which showed a very low sodium (something like 120), high potassium (maybe 6.3), and a high BUN. I thought the patient had Addison's disease – adrenal cortical insufficiency – and asked, "What are the urinary 17-hydroxycorticosteroids, and what are the 17-ketosteroids?"[4] The answer was one we might hear from the a hospital director concerned about DRG payments or from the managed care people today: "What do you want those for? You've already made the diagnosis, and you'd just be wasting money getting those tests. A really *good* doctor doesn't need all that lab work!" I felt mortified and embarrassed in the face of such an onslaught by a respected clinician – and me just a pseudochemist, and presumably a pseudoclinician as well. I went home depressed.

But I was wrong to give up so quickly. That was some 30 years ago, and over the years I've seen many more patients with similar problems – endocrine deficiency states, particularly *hypothyroidism*. A great many people in the United States take thyroid pills, and lots of them are referred to me for evaluation. Well, once somebody has been taking exogenous thyroid for a few years, it is next to impossible to tell whether they *initially needed it or not*, without going through an uncomfortable and prolonged withdrawal period, with multiple measurements of blood hormone levels, and even then you may remain uncertain. And this is *lifelong medication*! The same is even more true with a disorder like Addison's disease. The proper procedure answer in such cases is to *obtain the confirmatory laboratory tests at the time the diaanosis is first made*. If that is not done, there is no way another doctor 5 or 10 years later, after 5-10 years of replacement therapy, can tell quickly and cheaply whether the initial doctor was right or not. Thanks to the excellence of modern endocrine therapy, the patient is restored to essentially normal good health by treatment, and the original signs and symptoms disappear. One can only guess at what that doctor a decade ago might have found.

A good and appropriate Chemistry Profile is a necessary part of the Physical Examination just as much as a good systems review is part of a good history.

So I am a believer in your work, and I depend heavily on it, as do essentially all clinically active doctors these days.

One final point: Congratulations on entering a good and expanding job market! I am told that there are lots of jobs for medical technologists these days, even in the face of staff reductions, hospital closings, and the rest. But your work is almost without boundaries. Environmental pollution and protecting the environment are becoming major concerns. How are we going to define "environmental pollution?" By reference to *human beings* and *human physiology*. By *detecting and measuring* pollutants, estimating the purity of water (that is, levels of contaminants), and doing the other tests you now have the basic training for.

The Greeks, and later the Roman architect Vitruvius, and still later most West Europeans said *"Man is the Measure of All Things"*. And this means that we refer things to our own selves since we have only one pair or eyes.

So, your training in *detecting and measuring things* in the human body and in the environment will stand you in good stead all your life. And it will give you a good basis for employment — at least until you invent the next generation of instruments, become a multimillionaire, and retire to the Caribbean!

Congratulations, and good luck!

REFERENCES AND ENDNOTES

1. One might argue about when "chemistry" started, and the medical historians do argue.

The history of chemistry is probably about as old as human attempts to develop tools of any kind, to find a better metal, harder and better able to hold an edge than the old one, for a better sword or spear. Or maybe the *alchemy* of ancient Egypt and the Middle East should be considered the beginning, with its two aspects: one the attempt to transform base metals into gold, and the second (more important to us) the attempt to understand the *substances (or single substance) from which all material things, including our own bodies, are made*. Aristotle taught that all material things are made of four fundamental elements - Earth, Air, Fire, and Water. But very early on human beings developed an interest in all *natural products*, especially those from plants as well as minerals.

Paracelsus of the 16th century was one of our founders. His real name was Phillipus Aurelius Theophrastus Bombastus von Hohenheim, but he called himself "Paracelsus" or "one better than Celsus," the famous first century Roman physician. Paracelsus was the first of the "Iatrochemical School" of physicians, or those who placed their faith in *chemistry*. But the alchemists stuck to their Aristotelian "Four Elements" through the 16th and much of the 17th centuries, with much emphasis on the occult; and this situation remained till the rise of *mechanical philosophy* in the 17th and 18th centuries, led by Robert Boyle and Isaac Newton in England. We often think of this 20th century as "the scientific century," and indeed much science and technology did develop during this century. But it was really the *19th century* in which the basic sciences developed and in which medicine was transformed from being *occult and empirical* to *scientific and experimental*. The elements of not only modern chemistry and physics, but also bacteriology, radiology, nuclear medicine, and most of the rest of modern "scientific medicine" were in place before 1900 and the turn of this century.

2. Pittman, J.A., Jr.: RIA: An historical note. **Clinical Chemistry** 19:793, 1973.

As mentioned in this article, Berson and Yalow began working soon after World War II in the radioisotope laboratory of the Bronx Veterans Administration Hospital. Since ^{131}I was the main isotope used in clinical research then, and since the beginnings of a body of knowledge about radioiodine had been building during the war, they used this to study thyroid physiology. But, being very smart people, they realized that the future in endocrinology research would lie in problems of diabetes mellitus, not thyroid diseases; thyroid physiology and diseases provide interesting models and intellectual puzzles, but they infrequently kill or seriously maim anybody. Diabetes both cripples and kills people, and lots of them. So they used ^{131}I to label insulin, with which they did their experiments on the pathophysiology of diabetes in human patients.

3. This respected internist was *not* Tinsley R. Harrison, M.D., who had a very high regard for laboratory determinations as a basis for good clinical practice. Harrison is Alabama's all time best known physician, for whom the Tinsley Harrison Tower is named, where the Department of Medicine is located at UAB. There is a statue of him on University Boulevard just in front of the Tinsley Harrison Tower. He is best known for his textbook, **Principles of Internal Medicine**, which has sold more copies than any other text of medicine in the world.

Harrison got his 1925 job at Vanderbilt largely because of his excellence in running the clinical laboratory at Johns Hopkins. He then went on to run the clinical labs (all the clinical labs) at Vanderbilt for many years.

He always emphasized how important it was for the clinician to *understand* the lab work. He said, "Either you can make the lab work for you, or you will work for it. You can be the slave of the lab, or the lab data can be the slave for you."

4. In those days we determined both the 17-OHCS and 17-KS colorimetrically. We used the PS reagent for the former and the Zimmerman reagent for the latter. The PS reagent was named for Porter and Silber, who had developed it. It contained phenylhydrazine and sulfuric acid, which was convenient, since that was also "PS." In the presence of the PS reagent, the "PS chromogens" gave a pink color, the intensity of which was proportional to the concentration of the 17-OHCS. For the 17-KS we used meta-dinitrobenzene (the "Zimmerman reagent"), which gave a purple color with dehydroepiandrosterone, its metabolites, and other 17-ketosteroids. I once met Dr. Zimmerman, in Germany in 1960, and my wife danced with him at the banquet of the first International Congress of Endocrinology in Copenhagen. He had developed his 17-KS test in 1935 just before World War II and had survived through the war.

High Risk Behavior: Personal Freedom vs The Greater Good

*Andrea G. Summer, B.S., M.A.**

If, as the World Health Organization (WHO) has defined it, health is "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity," then high risk behavior would include all personal lifestyle choices that interfere in any way with that state of complete physical, mental, and social well-being. Utilizing the WHO definition, it is easy to see how virtually every lifestyle choice, whether it is the decision to engage in a high risk behavior or avoid a healthy one, could at some point serve to produce a lack of health. The issue of behavioral lifestyle choices takes on importance in the health care debate as evidence mounts that lifestyle choices contribute to the majority of illness in modem American society (Leichter 1991).

The question to be answered is how to balance individual freedom of choice with the greater good of society. Dr. James Gregory, an opponent of a bill in early 19th century England "To prevent the spreading of the infection of smallpox," argued that "England is a free country and the freedom which every freeborn Englishman chiefly values is the freedom of doing what is foolish and wrong and going to the devil in his own way." Much more recently, James Kilpatrick, arguing against compulsory installation of air bags in automobiles stated, that " a free people must be free to be foolish" (Leichter 1991). In spite of the strong emphasis on personal freedom in America, there exists that point at which our individual freedom to choose our lifestyle comes in conflict with the greater cost to society.

We have always been a nation of risk-takers. Where would our nation have been if the English government had refused to allow ships to sail to America because of the health risks and high mortality rates? How would our nation have developed if government had forbidden westward travel for the same reasons? We have always been a people who collectively were willing to take risks for our freedom. Why are we now a people who look to the government and the legal system to take responsibility for our own choices?

To answer that question, we have to take a look at the point at which your behavior becomes my business. The accepted concept is that when an individual life-style choice has consequences that extend beyond the individual by placing others at physical risk, causing them material deprivation, or limiting their freedom, and that choice is made by enough individuals, then that behavior is subject to public health policy (Hammerle 1992). Leichter (1991) states that the critical questions to be asked are: How likely is it that your foolishness will bring harm to others? What is the nature of that harm? How credible is the evidence linking the behavior to the harm?

This paper will examine several high-risk behaviors which seem to have had the greatest impact on society as a whole: smoking, alcohol and drugs, and sex. The focus of this paper is not to state the obvious, which is that these issues result in a myriad of health problems, but to present these issues from the point of view that perhaps they are not problems that the government needs to fix. In addition, several other behavioral lifestyle choices will be discussed from the viewpoint of those behaviors that are desirable but not legislatable in terms of the collective good. The second part of the paper will focus on the methods used to lessen high-risk behaviors and increase healthy behaviors. These include legislative efforts, educational efforts, and incentives. Lastly, I will argue against the use of the legislative process to control behavior and discuss the perils of looking to the government to provide health and the ramifications of government controlled health care on personal freedom.

Smoking

Smoking has become the scourge of health related behaviors. Once it was seen as sophisticated and glamorous. Who can forget the old movies where the heroes and heroines smoked languidly in front of the cameras? But, in the films of the '90s, when a person lights up, it is a sign of evil or weakness of character.

Smoking is generally accepted as the most serious public health problem of our time, accounting for somewhere between 390,000-500,000 deaths annually in the US (Leichter 1991; Hammerle 1992; Begay, Traynor and Glantz 1993; Gostin and Brandt 1993). More people die prematurely from smoking related diseases than from auto and fire accidents, drug

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abuse, homicide, suicide, and AIDS combined (Hammerle 1 992).

Nobody would argue that anyone should be encouraged to smoke. And while smoking may successfully be curtailed in public places, it will never be eliminated completely. Why? First and most important of these reasons is money. Tobacco typically ranks fifth or sixth annually in legal cash crops and first or second in value per acre. Worldwide cigarette production in 1990 was 700 billion cigarettes. In 1986 Price Waterhouse estimated that the US tobacco industry contribute $60 billion to the GNP. Tobacco core and supplier employees paid $2.35 billion in personal income taxes and $1.72 Billion in FICA taxes. Corporate taxes totalled $2.2 billion. And excise taxes on cigarettes contributed an additional $10 billion in taxes, of which 42% went to the federal government. Plus there are no tobacco subsidies — funding for price controls is entirely internal (Hammerle 1992).

The Office of Technology Assessment estimated the external costs of smoking to be $22 billion in health care and $38 billion in lost productivity (Hammerle 1992). But an interesting point was made that indicated~a sort of monetary windfall to nonsmokers – a net economic gain resulting from the fact that smokers die young sparing the cost of more debilitating disease and before drawing on social security and pension benefits. It was hypothesized that smokers may in fact reduce health care costs by dying more quickly (Hammerle 1992).

The second reason smoking will never be eliminated is that prohibition is not successful. It was not successful with alcohol. It is not successful currently with drugs. And it will not be successful with smoking. A society can make a substance illegal to use, but it can not prevent the use of that substance. A case in point centers around Canada's high cigarette excise tax, an effort to prohibit use economically. The result is increased smuggling of cheaper cigarettes across the United States - Canadian border.

The argument that environmental tobacco or second-hand smoke is a hazard to the nonsmoker redefines both the nature of the problem in terms of external costs and the range of acceptable policy alternatives (Leichter 1991). The effects of environmental tobacco smoke have taken the issue of smoking cigarettes away from the arena of the freedom to be foolish (Berger 1994) and moved the issue into the arena of my right to be foolish versus your right to breathe. Now the question is not: What is the proper role of government in protecting people against their own choices? but rather: What is the proper role of government in protecting society from an individual's choices when those choices pose a clear health risk to others? While government should not interfere with our right to be foolish, does it have an obligation to protect others from our foolishness?

Alcohol and Drugs

Dr. Benjamin Rush wrote "An Inquiry into the Effects of Ardent Spirits on the Human Mind and Body" in 1784, which detailed the many vices of intemperance including idleness, gaming, peevishness, lying, swearing, stealing and swindling, perjury, burglary, murder, puking, dropsy, epilepsy, and madness (Leichter 1991). The problem with alcohol is that unlike tobacco, which has no safe dosage, alcohol in moderation may in fact have health benefits Hammerle 1992). But, even a moderate drinker may occasionally overindulge or may drink and drive. Alcohol reduces inhibitions and people under the influence of alcohol are more likely to engage in other high risk behaviors. And who can determine who will become an alcohol abuser or alcoholic? While an estimated 100,000 people die each year in the United States from alcohol, alcoholism affects 18 million alcoholics and an additional 50-60 million "victims" including family members (Leichter 1991; Hammerle 1992). The internal and external costs of alcoholism including treatment, health care, mortality, reduced productivity, lost employment, motor vehicle crashes, crime, social welfare, and incarceration totalled over $117 billion in 1983 (Hammerle 1992). That figure is expected to exceed $137 billion by 1995.

Prohibition did not stop alcohol abuse. Alcohol consumption did decline but this was offset by reduced revenues and increased crime. We have no reason to believe that prohibition would be any more successful now than it was then. Ironically, we have prohibition policy toward drug use that is no more successful than was prohibition of alcohol. Drug use in the United States is escalating along with associated crime, high risk sexual behavior, and fear.

The so-called war on drugs has yet to make a dent in the illegal drug trade. There are some, including economist Milton Friedman, who advocate legalization with restrictions of drugs, arguing that the cost of addiction would be offset by reduced social costs (Hammerle 1992). Legalization advocates argue that crime would be reduced, billions in tax revenues would be generated, and quality and dose would be controlled (Hammerle 1992). Opponents of legalization argue that to do so would condone an encourage the use of drugs and that drug usage would rise (Hammerle 1992). Can the problem be any worse with legalization than it is now with prohibition?

Sex

High risk unprotected sexual behavior has been associated with health risks since World War I when doughboys were urged to "control themselves" and stop the spread of venereal disease (Leichter 1991). The federal government responded by prohibiting prostitution in areas adjacent to military facilities

raising the issue of how far the government could go to restrict the rights of those who might threaten the greater good (Leichter 1991). The potential health risks today are far greater with AIDS with an estimated 1,000,000 Americans HIV – infected in 1992 (Hammerle 1992).

In 1991 $10 billion was spent on HIV related activities. Federal expenditures topped $3.46 billion spent on research, medical care, education, and income support. The cost of treating an HIV+ person is $5,150 per year and the cost of a full-blown AIDS patient is $32,000 per year. Average lifetime care of an AIDS Patient is expected to reach $200,000 per year (Leichter 1991; Hammerle 1992).

As with the other high risk behaviors, there is no way to effectively legislate sexual behavior. In 1984, the public health director of San Francisco closed nine gay bathhouses and clubs because they encouraged the behavior that spreads AIDS. A superior court reversed the ruling (Rabin 1986). The point is that closing bathhouses or clamping down on prostitution does not change behavior — those actions just make more criminals. It is not the government's role to impose morality on its citizens. It is the government's role to provide as much objective information as possible to its citizens in order for them to make educated, rational lifestyle choices.

Gold Star Behaviors

Much disease is self-inflicted, a product of our habits. Through negligence, self-indulgence and irresponsibility we contribute significantly to our own early demise. As such, we, through personal responsibility can do more to insure our own health than can any doctor (Hammerle 1992).

Health care policy needs to focus on incentives that will encourage healthy eating, regular exercise, wearing seat belts, safe driving, and other behaviors known to promote health. But can we be made to behave responsibly? And will we widen the gulf between those who are educated and economically secure (the group statistically more likely to engage in healthy behaviors) and those who are poor and less educated (Hammerle 1992; Salsberry 1993)? Will we become more of a class conscious society as those who practice responsible lifestyles look down their noses and hide their wallets when confronted with those who have acquired behavior related diseases? Are sick people sinners who need government to protect them from themselves? Do they in fact deserve to be sick (Leichter 1991; Hammerle 1992; Fitzgerald 1994)?

Public Policy - Legislation

Proposed and successful legal efforts to control risk behaviors include restriction of cigarette advertising and promotion, restriction of smoking activity, restriction of sales to prevent minors from buying, modifying the product, regulating the cigarette industry, and increasing the excise tax (Leichter 1991; Hammerle 1992; Begay, Traynor and Glantz 1993; Gostin and Brandt 1993; Jacobson, Wasserman and Raube 1993; Schauffler 1993). How successful have these efforts been? While overall cigarette usage has declined, teenagers are taking up smoking at increasing rates (Hammerle 1992). What teenager can't find a clerk to sell them cigarettes or beer when they want it? True, smoking is not permitted on airplanes or in many public places but have those legislative efforts been the impetus behind any individual decision to quit? The question is: Would people quit smoking because it was against the law? And conversely: Would people refrain from smoking in the first place if it were against the law? For some, increased taxes have been a reason to quit. For others, the inconvenience of smoking was enough. How many smokers have looked at the warning on their cigarette packs and suddenly saw the light and threw away the evil weed? Smokers quit smoking because they make a decision to quit. That decision cannot be legislated. It is a personal choice.

Have we been any more successful with legislation aimed at curbing alcohol abuse such as tougher drinking and driving laws? How many people after a few drinks decide to leave their car and call a cab or walk home? Alcohol releases inhibitions and makes the drinker feel more invincible. Sure, more people are drinking responsibly, but those were most likely the people who were not causing a significant problem to begin with (Leichter 1992).

And of course, laws prohibiting prostitution have been notoriously unsuccessful. Some behaviors just do not lend themselves to successful legislation. And when we give government the power to legislate one behavior, how can we prevent that same government from attempting to legislate all behavior? Smoking is the issue of the '90s. What's next? Alcohol? Fatty foods? Will the corner bar become a thing of the past as anti-alcohol forces petition for tougher laws? Will fat-crazed adults sneak through grocery stores with their twinkies hidden underneath the lettuce? Will drinkers gather furtively in doorways as smokers do now, huddled together in their common sin?

Public Policy - Education and Incentives

Behavior related health policies need to focus on three areas: higher excise taxes to provide funding for education and treatment (Hammerle 1992; Leichter 1991; Marwick 1994), preventive education (especially targeted toward young children) (Hammerle 1992; Skolnick 1993), and incentive programs instigated by employers and insurance companies (Hammerle 1992; Schauffler 1993; Begay, Traynor, and Stanton 1993; Gomel et al 1993).

Higher excise taxes on products associated with increased costs to society are inevitable. Those who engage in high-risk lifestyle choices must be willing to take responsibility for those choices, including paying now for future health care costs. Taxation is also appealing because there is strong evidence correlating increased cost of cigarettes and alcohol to decreased consumption. Therefore a punitive health tax would both defray costs and discourage use (Leichter 1991).

Arguments against higher excise taxes center around issues of fairness, questioning whether higher use taxes penalize those who, by addiction, have no control over usage. The other issue of fairness is the inclusion of only alcohol and cigarettes and not all substances which may have an adverse effect on health (Leichter 1991).

Prevention strategies are effective in the long run. The majority of smokers today are those who started smoking before any educational efforts were begun. More people are quitting smoking today as a result of educational efforts and fewer are starting (Hammerle 1992).

In a free market society, as fewer and fewer people smoke, the tobacco industry will diversify with little or no loss of jobs (Hammerle 1992). In a government controlled society, if smoking is banned, those who are employed in the tobacco industry will be out of work. In a free market society, providing people with personal and financial incentives in the form of reduced health care premiums, time off, or financial bonuses will stimulate responsible employees to responsible behavior. In a government controlled society, mandating behavior spurs dishonesty and corruption as people try to get around the system. Anyone who has ever had a teenager knows that to forbid a behavior merely teaches the child to lie in order to avoid the consequences.

Behavioral therapists are in agreement that punishment is the least effective means with which to being about significant behavioral change (Martin and Pear 1992). Positive reinforcement is generally credited with being the basis for successful behavioral change. The principle underlying positive reinforcement is that a person knows that when a desired behavior is exhibited, a reinforcement will follow (Martin and Pear 1992). Utilizing this concept, some corporations and insurance companies have begun to offer incentives to employees who cease risktaking behavior or who engage in healthful behavior (Warner 1990; Gomel et. al 1993; Schauffler 1993).

Some of the incentives offered for behavioral change include risk rated health insurance premiums and provision for insurance coverage for smoking cessation services (Schauffler 1993), lottery draws for participants in a wellness program and $1000 prize for the department with the largest number of participants meeting wellness goals (Gomel et. al 1993). The point here is that these incentives are provided for by private industry with increased healthy behavior and decreased health care costs as the common goal. There are no mandates. Employees can choose to participate. While the initial cost of setting up such programs may put off many companies, the overall reduction in health care claims will provide the impetus for more participation (Schauffler 1993).

Conclusion

We are a society that has always valued our freedom, at times above life itself. There is no argument that high-risk behavior entails a cost to more than the individual. We are becoming a society that not only wants guarantees against disease, aging, and death, but we government to provide those guarantees (Fitzgerald 1994). And we are now trying to make a distinction between socially acceptable and socially unacceptable lifestyle choices despite the knowledge that all lifestyle choices will inevitably lead to the end of life (Fitzgerald 1994).

It is important for those debating health care reform to remember that whoever pays the piper calls the tune. If a national health care policy passes, government pays and government controls. There is a tongue-in cheek story about the last healthy man – he takes no risks, eats only healthy foods, exercises regularly, avoids all stress, is tested regularly for disease (always negative of course) and has been deemed normal in spite of all his efforts at different therapies (Meador 1994). Is this the future of our society? Is it so important to us that we all enjoy perfect health all the time, that we judge each other by our healthful activities or lack of them?

The United States has become a country obsessed by health. We take ourselves far too seriously when we presume the ability to dictate human behavior (Fitzgerald 1994). In order to dictate human behavior, it must first be judged as either worthy or unworthy. Who will be the judge? If there is the one perfect person who makes only healthy lifestyle choices, who has been deemed disease free, is that person qualified to deny people charity, empathy, and understanding because their actions have made them sick (Fitzgerald 1994)?

In the ongoing debate concerning health care, it must be remembered that we are a nation with a collective soul grounded on the principle of freedom. Children and those incapable of protecting themselves need to be protected from their own foolishness and the foolishness of others. The rest of us just need the facts. Let the government label everything. Let the government publicize every study that has ever been done about anything. And then let the people decide.

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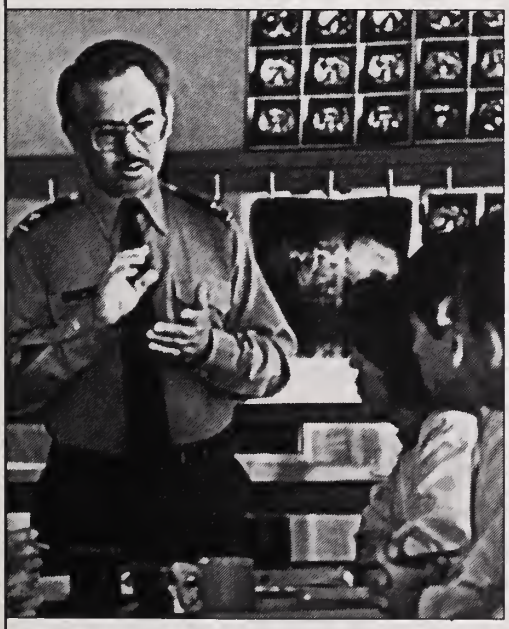
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Alliance Health Projects

It would be difficult, if not impossible, to cover in one report all of the extensive health projects being sponsored by alliances/auxiliaries across the state of Alabama. The numerous action projects help improve the health and well-being in their surrounding communities. The following are highlights of many successful health endeavors for the 1993-94 year and was submitted by Mrs. John O'Toole, 1993-94 Health Committee Chairman.

Lauderdale County sponsored a program in local schools on the prevention of head and spinal cord injuries in children, with the participation of a person who had received a severe spinal injury in an accident. Other counties placed tapes on the prevention of football injuries in the physical education department of their local school systems. Still others presented programs on bicycle and gun safety. Houston County Medical auxiliary distributed safety brochures on the importance of bike helmets and car seats to the local bike shops, Toys-R-Us and pediatricians' offices.

Many alliances worked in local schools providing coloring books for second and third grade classes addressing issues of self-esteem, drug prevention and physical fitness; AIDS Awareness seminars; offering volunteer assistance for tutoring; providing much needed equipment; and offering many other services to improve the health of our school age children. Colbert County presented a program at the elementary schools in conjunction with the Great American Smokeout that featured Smoking Sam. They also presented a program for parents entitled "How to Talk to Your Children About AIDS." This program, held at the local health department, had a doctor, counselor and HIV positive patient on the panel.

Etowah County passed out Hotline Cards to all seventh grade students. The Auxiliary also helped to fund the first AIDS Hospice in North Alabama.

Scholarships were provided for students in a medical-related field in many counties. Much effort and time goes into planning the fund-raising events that provide thousands of dollars to fund these scholarships.

Immunization clinics were sponsored by auxiliaries throughout the state and have been more successful each time. Lauderdale County sponsored four different clinics and dispensed 306 vaccinations at the last clinic. The Montgomery-Autauga-Elmore Auxiliary donated approximately $800 to the Montgomery Area Council on Aging to purchase flu vaccine for indigent senior citizens, as well as assisting with paperwork while nurses administered the vaccine.

Most counties do extensive work educating the public on the importance of mammography. Morgan-Lawrence County Auxiliary provided free breast screening for low income women, prescription drugs for low income patients and hospice groups; provided a TV/VCR for a local hospital and a diaper bag program at Lawrence County Hospital. They also gave financial support to the Parents and Children Together, a local agency for the prevention of child abuse and neglect.

All counties were encouraged to implement the "buddy system" where two friends agree to call each other once a month as a reminder to do a breast self-exam. Billboards were placed in various parts of the state to encourage women to get mammograms.

Mobile County put information on early detection and self-examination in offices of 60 physicians and in the dressing rooms of 15 department stores. Marsha Folsom, Alabama's First Lady, participated in the American Cancer Society's Breast Cancer Awareness

Walk.

Several major projects are on-going in our state and require much dedication and effort on the part of alliance members to keep them active. The Houston County Medical Alliance main project is the Chrysalis Home, a permanent foster care facility for abused or neglected girls 13-18 years of age. The goal and responsibility of the home is to provide a loving and nurturing home for these girls that will shelter, heal, teach and love as the girls grow and build self-esteem. This year alliance members raised over $33,000 for Chrysalis.

The major project of Mobile County is Camp Rap-A-Hope, a free camp for children ages 7-17 with cancer. 150 physicians and spouses are involved each year, and planning continues year-round. Although nearly every event at the camp is unique and exciting, the highlight for the summer of '93 was Prom Night with donated formals remade to fit the girls and vests and top hats for the boys. The evening was complete with limo rides and prom pictures for everyone.

Jefferson County presented Body Trek, a mobile health education facility, to over 14,000 children in Birmingham-Jefferson County area. "Someone To Talk To," Jefferson County's child abuse education program, is designed to show children in a non-threatening, non-judgmental environment, how to tell a responsible adult if there is a problem in their life. The puppet show was presented to 47 schools involving 2,300 children. These volunteers are training other county alliances how to use the puppets in their schools. HealthLine, co-sponsored by Liberty National Life Insurance and Channel 6 TV, was a terrific success with physicians taking calls from over 3,350 Alabamians, with an eleven year total of 55,000 calls.

Pickens County presented their local hospital with two baby manikins to be used as an educational tool for new mothers, along with the film "Babies First Days."

In addition to other counties, Talladega County contributed money to the Alabama Child Care Foundation to sponsor health care for children who have no health insurance coverage. When the alliances provide money to sponsor a child, Blue Cross and Blue Shield of Alabama will match the gift dollar for dollar.

Lee County worked very hard to raise money to give to Habitat for Humanity for local housing projects.

Family Violence Shelters throughout the state have been supported by many alliances donating money, clothing, supplies and equipment. Montgomery-Autuaga-Elmore Medical Auxiliary gave over $10,000.00 to their local center.

Major fund-raisers were conducted to provide financial aid to the Child Advocacy Centers across the state. Madison County sponsored Children's Celebration, a street fair in front of the center with food, puppet shows, games and exhibits of the community areas in which the Alliance is involved. They are also working hard to build a Hands-On Science Museum. Their goal is to provide an endowment of $50,000.00 matched by funds from the Medical Society.

International health projects are continuing in our state with two projects supported by the alliance. The first is El Amparo de San Jose, a nursing home located in the western highlands of Guatemala, to which we send financial aid. The second involves Casa Guatemala, a private orphanage dependent entirely on contributions, which supports abandoned and abused infants and children. Our International Health Committee works with MASA to send Alabama physicians to Guatemala to help the children. In addition, antibiotics and some equipment were sent to be used in their clinics.

Although our state has many different sizes of county alliances, ranging from six to 353 members, we're all working very hard to identify, address and support the health care needs of our communities. These dedicated and concerned alliance/auxiliary members are truly a positive force in promoting health care in Alabama.

Hospital Medical Staff Section
24th Assembly Meeting
December 1-5, 1994
Sheraton Waikiki Hotel
Honolulu, Hawaii

Representation Education and Networking

Send a representative from your hospital medical staff and physician organization to the 1994 Interim American Medical Association Hospital Medical Staff (AMA-HMSS) Assembly Meeting held on December 1-5 in Honolulu. Aside from participating in the development of AMA policy, representatives will have an opportunity to network with colleagues, dialogue with the AMA Board of Trustees, and hear the latest news and information on health system reform.

With a changing health care environment, broader diversity within the physician population, limited resources, and an overriding need for unity of purpose and action by organized medicine, the AMA has undertaken a study of the Federation.

Federation Consortium Study

The study, involving county, state and specialty societies, the AMA, and other related organizations, intends to uncover useful information for developing ways to increase membership, member participation, and advocacy as well as improve communications, medical society performance, and resource utilization.

Project leaders have asked the AMA-HMSS to participate in the process because it effectively represents grassroot physician concerns. Input from each HMSS representative also will be extremely valuable in defining organized medicine in the future.

The 1994 Interim AMA-HMSS Assembly Meeting Education Program will host the Consortium study. Data collected and analyzed will facilitate the following objectives:

- Identify current and future needs, expectations, and preference of physicians and others for organized medicine;
- Explore membership ideas and options;
- Assess how medical societies relate to each other—including ways to be more supportive, avoid duplication of effort, leverage strengths, and better address weaknesses;
- Discover whether there are better tools/technologies that medical societies can use to communicate with one another and their members; and
- Enable medical societies to work smart in a more focused and purposeful way.

Plan to participate in the Federation Consortium on Friday, December 3 from 2:30 to 5:30 pm in Honolulu, Hawaii. Mahalo!

American Medical Association

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Special Notice - Call for Papers

The Medical Association of the State of Alabama

Eleventh Invitational Scientific Symposium

Saturday, January 28, 1995 - 9 AM to 4 PM
Edna Merle Carraway Convention Center,Birmingham

Purpose of the Program - This program is designed to allow Alabama physicians to share with their colleagues current research efforts and professional concerns. Topics selected will cover a wide range of medical interests.

Program Format - The program will be structured from the papers submitted by Alabama physicians. Registrants will receive copies of all papers.

Paper Selection - Papers will be selected using the following criteria and procedures:

1. The subject matter should be of interest to physicians in a number of specialties. Emphasis should be on medical problems which may be encountered by primary care physicians.
2. This is a program designed for and presented by Alabama physicians, so current local research efforts and professional concerns will be given top consideration.
3. The paper should be one that can be adequately outlined and covered in 20 minutes with additional time for questions. Selectees will be expected to prepare suitable written materials to be used with the presentation for the study and use of attendees.
4. On the final review of papers, members of the MASA Council on Medical Education will select topics from a variety of specialties and physician interests to offer a balanced program of general interest.

"Excellence in Teaching Award" - After the meeting, attendees and the Council on Medical Education will select one presenter for a special teaching award based on teaching skills in presenting information, and quality, clarity and helpfulness of teaching handout materials.

Symposium Timetable

August 15 to November 1, 1994 - Call for abstracts
November 1, 1994 - Final date for abstracts to be received
Early November 1994 - Review of abstracts by the Council on Medical Education and final selection of papers.
November 1994 - January 1995 - Announcement of selections, publicity and promotion of Symposium; Printing of abstract and handouts.
January 28, 1995 - Program presented in Birmingham at Carraway Convention Center

Symposium Topics - to acquaint potential presenters with the kinds of subjects that might be suitable, the speaker and topics at the 1994 Symposium are listed below.
Guy H. Handley, MD - Evaluation and Treatment of Chronic Sinus Complaints; BJ Kraynack, MD & Jaro Mayda, MD - Topical Clonidine Treatment of Postherpetic Neuralgia; Richard Jennelle, MD - Stereoatic Radiosurgery: A Multidisciplinary Non-invasive Surgical Technique; Steven Stokes, MD, et al. - Transperineal Ultrasound Guided Radioactive Seed Implantation as Treatment for Localized Carcinoma of the Prostate in Medically Inoperable Patients; Gregory W. Cotter, MD - Changing Trends in the Treatment of Early Breast Cancer; Ruby Meredith, MD, et al. - Intraperitoneal Radioimmunotherapy for Ovarian Cancer at UAB; Jerry McKnight, MD, et al. - Survey of Alabama Adolescent Sexuality: A Comparison with National Data; Karen Landers, MD - Diagnosis and Treatment of Congenital Facial Deformities; Jonathan S. Pendergrass, MD - Symptomatic Breast Hypertrophy and Breast Reductions Surgery; Keith Parker, MD and S. Hutson Hay, MD - Analysis of Generated Retinal Reflexes; W. Douglas Everett, MD - Colposcopy and LLETZ in a Family Practice Residency Program

Abstracts - abstracts of proposed paper (200-300 words, doubled spaced) should be sent to the Council on Medical Education.

Submission of Papers - Interested presenters should send abstracts to the **MASA Council on Medical Education P.O. Box 1900. Montgomery, AL 36102** no later than November 1, 1994

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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month – day of month if weekly – and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

Illustrations: Illustrations should be numbered consecutively and indicated in the text. The number, indication of the top, and the author's name should be attached to the back of each illustration. Legend should be typed, numbered, and attached to each illustration. Photographs should be clear and distinct; drawings should be made in black ink on white paper. For photographs, glossy prints are preferred.

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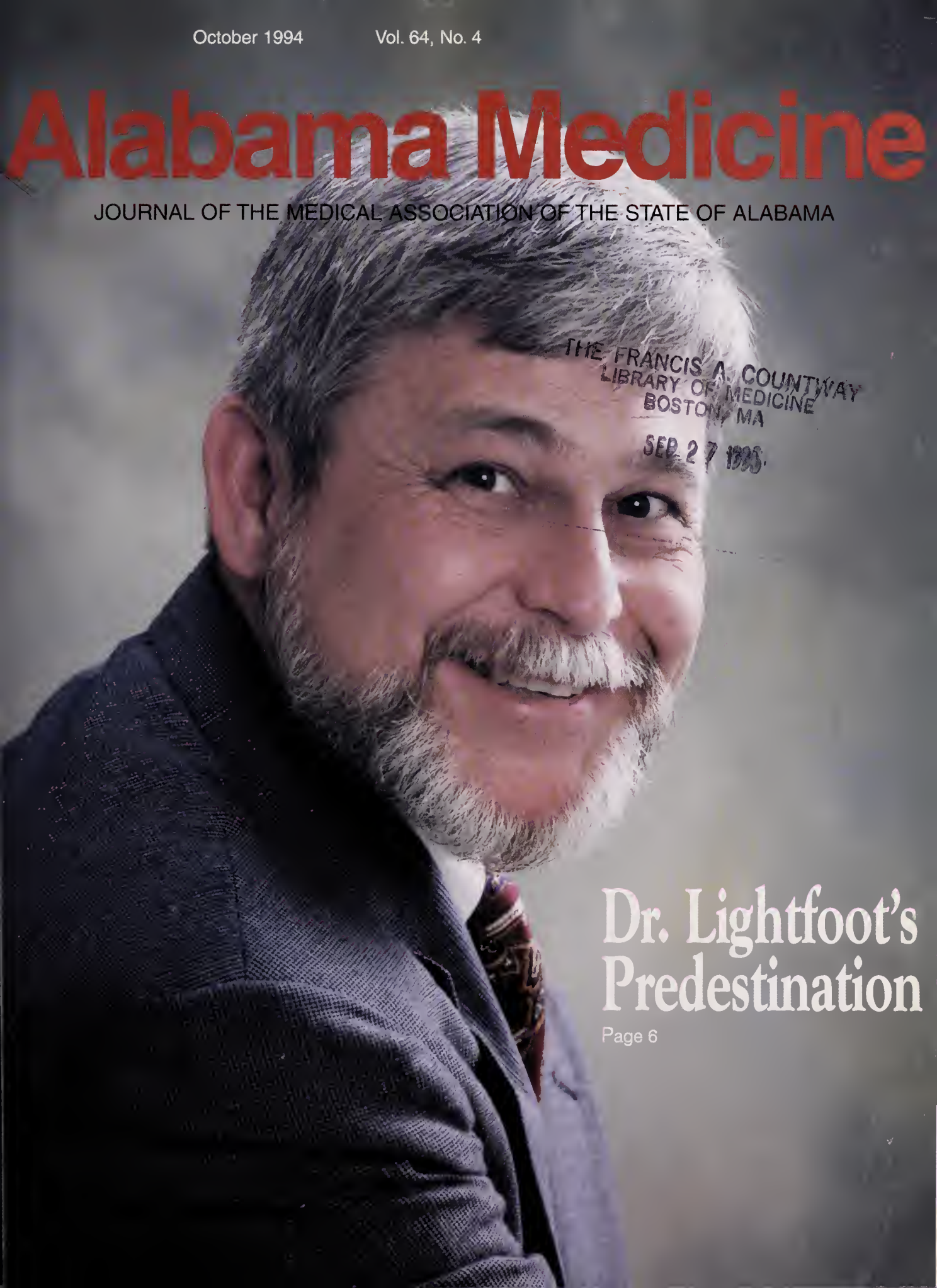
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Dr. Lightfoot's Predestination

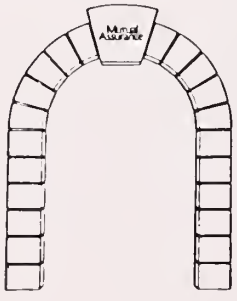
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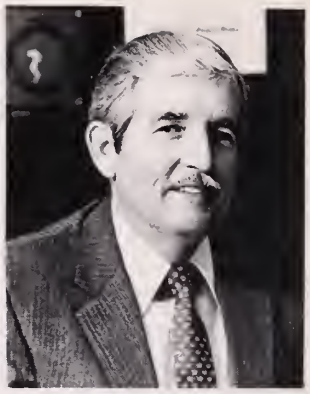
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Mission Impossible

Hindsight being a universal gift, many people are now saying they knew all along that comprehensive overhaul of the American health care system would not fly.

Not to embarrass any of these latter-day prophets, but I can't recall anyone who said that in early 1993, in the heady days after the coronation of the Clintons. Had such a prophet existed, he or she would have been reduced to humble silence by Mrs. Clinton's star performance before House and Senate Committees in the fall of last year.

Learned men in both parties spoke of the "aura of inevitability." And that included such current critics of reform as Senator Dole, who was falling all over himself a year ago to get on the reform bandwagon. In all fairness, it should be added that the American Medical Association, long in the vanguard of the reform movement, also did something of an about-face. AMA decided in the summer of '94 that its best interests lay in a substantial retreat from its earlier insistence on such absolutes as universal coverage.

What happened? One of the things that happened is that everyone involved got a fairly advanced post-graduate course in the daunting economics of the healthcare marketplace. Even the boldest adventurers of a few years ago must have learned that perhaps never before in our national history had anything of this magnitude and complexity been seriously addressed.

In the heat of the summer just past the emerging consensus of public and congress alike seemed to be that if this elephant was to be eaten, in the famous maxim of General Creighton W. Adams, it could only be eaten one bite at a time. The pejorative connotation that "incremental changes" bore a year or so ago did a slow fade, replaced by a belief in that process as perhaps the best way to go.

Several years ago, in reference to another Mexican stand-off in Congress, Mr. Dole observed that "a little gridlock might be good from time to time." I think that opinion has now been vindicated. Congressional gridlock, if you want to call it that, has saved the country from both the reckless revolutionary change proposed by the Clintons as well as the casual tinkering suggested by political opponents.

Of course there is still time for Congress to screw things up just for bragging rights in the November elections, but the passion to "do something even if it's wrong" has unquestionably subsided.

Subsided also is the public demand, devil take the hindmost, for immediate and radical action. Still, despite the disenchantments, those who earn their bread feeling the public pulse tell us that support for meaningful, sensible reform is still strong.

One element in that support is the creeping realization of just how much health care costs the average American. The prolonged debate itself created that realization. Counting Medicare taxes, private insurance premiums, out-of-pocket expenditures, etc., the Urban Institute has computed that the average American family is paying about $9,600 a year for health care.

That's a heavy burden in a country where real wages have not substantially increased in several years. And because it is a heavy burden, the public pressure for reform is not going to die tomorrow even though citizens have come to understand, in a fuzzy general way, the truth of management guru Peter Drucker's finding that "we may be nearing the end of our hundred-year belief in Free Lunch."

What really assured the legislative paralysis in Washington, however, was that scores of special interest lobbyists, 1,162 strong, descended on Congress with hands outstretched. Each had its own zero-sum agenda which said, quite simply, "We want this and we won't take that." None of them was prepared to

share in any genuine sacrifice for the common good. It was all gimme-gimme.

Each had barrels of money, more money than has ever been spent on proposed legislation. And with reason: on the table were plans to divvy up $1 trillion — the U.S. expenditure on health care goods and services.

Such numbers, and the avarice produced thereby, generated a kind of mob psychosis not unlike the mass mania that followed the discovery of gold at Sutter's Mill early in 1848. From consumer groups to some professional organizations, whatever their ostensible motivation, most were primarily driven by the same lust for loot that sent 40,000 prospectors to California almost 150 years ago.

Each of the lobbies had, in addition to its list of wants, certain non-negotiable positions. For example, the largest private provider of hospital services in the U.S. is the Catholic Church. On record in support of universal health care since 1906, it had much to gain if the poor it has served in such an exemplary fashion could be subsidized under universal care. But Catholic bishops said they could never accept legislation subsidizing abortion. And they meant never.

Now I happen to admire individuals and groups standing on moral principle, even when I might disagree with them. But the Catholic positions were mutually exclusive: congressional observers agreed there was no way on earth enough votes could be assembled to pass a comprehensive reform bill with universal coverage without also covering abortion.

Multiply this ambiguity hundreds of times, as each of the lobbies stated its respective parallel demands and taboos, and you have a perfect design for paralysis. To every adamant stand there was an equal but opposite one — canceling out to absolute zero.

Add to this the glaring truth that no one bending the ear of Congress wanted to pay for anything or make any meaningful sacrifice in return for something — and gridlock is almost a mathematical certainty.

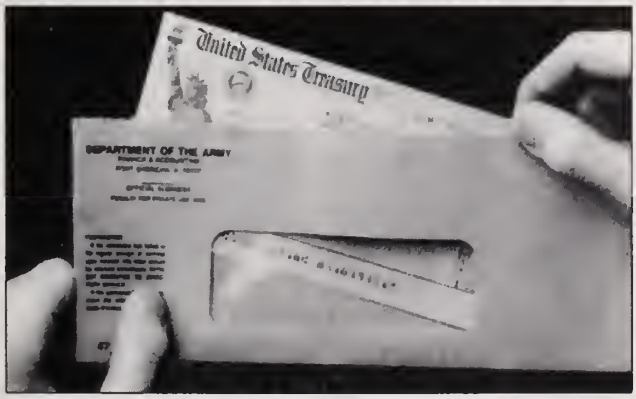
But is that a tragedy? No, not in my judgment. In whatever way it came to pass, the country was saved from the monumental ruin that would have resulted from anything approaching the Clinton plan. And the country was also saved from some smaller disasters mindlessly offered as more modest substitutes.

As Mr. Dole said, a little gridlock might be good from time to time.

This was such a time.

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PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

'The Southern Thing'

Let me preface the following comments with a disclaimer: I lay no claim to political science as a subspecialty — or, for that matter, a serious avocation.

That said, I would like to offer my theory, which is not original with me, of the essence of Mr. Clinton's problem, not only in his failure to convince the American people that his health reform plan was sound, but in all his attempts — and Mrs. Clinton's —at moral suasion. Remember that the predicate they laid before presenting the Magaziner monstrosity was essentially this: it was the right thing to do.

We could only infer from this that their argument was grounded on the Judeo-Christian concepts of human dignity and the sanctity of man. Having premised their case on such a lofty pinnacle, they in effect said that only a churlish knave could question the pristine purity of their motives.

Last fall, when Mrs. Clinton was making the case for the Clinton plan, central to her argument was this categorical imperative. And she did offer forceful and eloquent arguments, as evidenced by the awed deference accorded her by Senate and House Committees, one of which gave her an unprecedented standing ovation.

Then came the Clinton's bleak December — Whitewater, suspicious profits from commodity futures, Paula Jones and other assorted skeletons in their closet. This evidence of greed and libertine lifestyle did nothing to strengthen their moral posturing; public support for the Clinton health plan, never too powerful, began to erode as 1993 came to a close.

But public distrust goes far deeper than their peccadilloes. No writer on the American scene has done a better job of presenting the basis for this distrust, stripping away the President's ethical pretensions, than a good old Alabama boy whose name until recently was hardly a household word anywhere, least of all in his native state. His name is Howell Raines, Alabama born and bred, editorial page editor of *The New York Times*, far and away the most influential newspaper in the land and on most lists as the world's greatest newspaper.

Mr. Raines is a certified liberal, but an honest one. He trumpeted for massive health care overhaul long before Clinton made it a campaign issue. He wrote *Times*' editorials supporting Clinton for president. But he has been rawhiding Clinton ever since he took office — for all the reasons that hit the president hardest: his conniving, his retreats from principle, his abuse of the powers of office, his weakness and his myopic vision.

In essence, Mr. Raines has charged — to the consternation of the liberal community in New York and Washington and to the utter discombobulation of the Clinton White House — that Mr. Clinton's public probity can best be compared to that of Richard Nixon. This administration, *The Times* has said, is "easily the most reckless in interfering with the integrity of federal investigative agencies since that of Richard Nixon."

How could the Clintons' most influential supporter be doing this to them?, Bill and Hillary have anguished. Since Mr. Raines is a liberal, they moan, and has agreed with the administration's position on issue after issue, surely the *Times* editor has taken leave of his senses.

In fact, *The Times'* thundering assaults on the integrity of Mr. Clinton's administration have shaken what remains of the liberal establishment in the country. *The New Yorker* magazine recently addressed the question in a lengthy and agonizing essay on Mr. Raines and concluded that his apostasy was all a great mystery.

It's no mystery at all, comments Paul Greenberg, editorial page editor of the *Democrat-Gazette* in Little Rock. In a column syndicated in Alabama newspapers (Aug. 31) Mr. Greenberg wrote:

"It's hard to believe that even *The New Yorker* has failed to notice that Bill Clinton is doing to liberalism what Richard Nixon did to conservatism: Reduce it to an empty adjunct of his own political viability, thus depriving a vibrant political philosophy of constancy,

legitimacy, conviction, integrity, moral force ... and a fair chance of working.

"Not till after the memory of Tricky Dick faded did American conservatism revive.Who knows when or whether an authentic American liberalism will rebound after Slick Willie has hollowed it out?"

The best Clinton's aides have come up with by way of explaining Mr. Raines' motivation is to say that "it's a Southern Thing." That's supposed to convey a kind of yokel internecine hostility, I take it, such as southern football teams display as they go about the serious autumnal business of creaming each other.

It *is* a Southern Thing, Mr. Greenberg writes in his column, but not in quite the same way as the administration's put-down was meant to convey. Mr. Greenberg:

"The Southern Thing is embarrassing to have to explain, because if one has to use words to argue for honor, for character, for duty, for a code that words can only hint at ... well, it's just embarrassing. Like having to point....

"Strange: the Southern Thing is not a matter of words — often it is expressed by a heavy-laden silence — yet it may explain why the South has become the great incubator of American writing in this century. In the South ... meaning still attaches...

"An Alabama boy may recognize something about a politician or an administration or a whole fin-de-siécle age with so merciless a clarity that there is no *not* saying some things

"How could a Southerner help but react to the slippery maneuvers, verbal and political, of the New Age? The new, flexible, up-to-date standards of truth and honor on display in the Whitewater follies would be instantly recognizable to any Southerner with a sense of history; today's yuppies are yesterday's carpetbaggers.

"For that matter, Southerners of all regions understand. All it takes is a *code* of one's own that takes precedence over any personal advantage."

(Re-read that last sentence: "All it takes is a code of one's own that takes precedence over any personal advantage." That would seem to apply with equal force to physicians. We can be guided by our personal, professional and regional codes of honor, integrity and duty, or we can join the ranks of the hucksters and sharp operators, epitomized by the Clintons.)

In my mind, Mr. Clinton's fatal flaw is a quick study: he simply does not inspire trust. And his health care reform plan was just another fraudulent attempt to gain an enormous personal advantage as the brilliant architect of a radical revolution. He sought fame at any price.

History records many such opportunists. No better authority can be found for that than in a slender volume, *The Lessons of History*, by Will and Ariel Durant (1968, New York, Simon & Schuster). The Durants had spent their lives on the massive, multi-volume *Story of Civilization*. Their publisher had asked them to sum up in a small book the major lessons they had learned from man's long striving toward order and harmony. Here is one of them:

"Intellect is therefore a vital force in history, but it can also be a dissolvent and destructive power. Out of every hundred new ideas, ninety-nine or more will probably be inferior to the traditional responses which they propose to replace. No one man, however brilliant or well-informed, can come in one lifetime to such fullness of understanding as to safely judge and dismiss the customs of generations after centuries of experiment in the laboratory of history..."

Dr. Lightfoot's Predestination

William H. McDonald

[Cover]

The first contact with Alabama medicine that William (Bill) Malcolm Lightfoot, M.D., can remember was being in a Mobile hospital at age 4 with pneumonia. History does not record whether or not he was impressed.

His father, Robert Malcolm Lightfoot, M.D., then recently graduated from the University of Alabama School of Medicine, had moved his family with him to Mobile for his postgraduate training.

Young Bill could not have known it at the time, but he was destined (if not genetically coded) to become a physician himself — the fourth generation of the Doctors Lightfoot.

Forty-two years later, Dr. Lightfoot, a surgeon in private practice in Mobile for the past 15 years, is Chairman of the Board of Censors.

He was the first Censor to have made his way to the Board from MASA's Young Physicians' Section. (The second was Regina Benjamin, M.D.) And, at a youthful 46, Chairman Lightfoot is living refutation to the fatuous canard that the Board is fossilized. ("I am a Young Physician Emeritus," he insists with a boyish grin.)

The patriarch of the Lightfoot medical lineage was John Steele Lightfoot, M.D., who trained at the University of Nashville in the mid-1850s and practiced at Shorter, Macon County, in the heart of the Cotton Kingdom then thriving in that fabled crescent of rich, dark soil known as the Alabama Black Belt.

His son, Philip Malcolm Lightfoot, M.D., a 1900 graduate of the University of Alabama School of Medicine at Mobile, also returned to Macon County to practice in Shorter, as did his son, Robert Malcolm Lightfoot, M.D., Dr. Bill Lightfoot's father, who graduated from the UAB School of Medicine in 1952.

Born in 1948, Bill attended the first grade at Shorter but the second grade in Montgomery after his grandfather died. Bill's father, Dr. Robert, had moved his family the short distance to the capital city, where he practiced until his death in 1982.

Bill's mother, Alice, a Californian who met her husband during his World War II service in the Navy, still lives in Montgomery and sees her Mobile son at least once a month when he returns for Board meetings.

Bill was a member of the first high-school graduating class of the Montgomery Academy in 1966. With a graduation gift of money from his grandmother, he bought a Gibson guitar (Model J-45), which he still plays.

"It sounds better 28 years later," he says, "though I don't think I play it much better." Although he has never taken a lesson, Dr. Lightfoot candidly confesses to a fantasy that he has been a kind of "closet rock & roller," but his present interest is religious music.

From his mother, he inherited other pursuits he still finds relaxing — reading, stamp collecting, cross-stitching and needlepoint. Of the latter two, he says: "I haven't worried about the non-macho image since I learned that Roosevelt Grier [the humongous former pro football player whose seismic exploits on the playing field were the stuff of legend] also does needlepoint."

Dr. Lightfoot's great grandfather and grandfather were true country doctors, "doing everything country doctors did in those days." His father was a general surgeon as well as a general practitioner.

"When I was a child, my dad was often away from home. To be with him, I made rounds and house calls with him on weekends. So I had grown up in that kind of practice. I wanted to do what my dad did — general practice and general surgery. But by the time I had to make a choice, I couldn't do both."

After receiving his M.D. degree from UAB School of Medicine, he was headed for a Family Practice residency in Huntsville when he interviewed with Dr. Arthur Donovan, then Chairman of the Department of Surgery at the University of South Alabama College of Medicine.

Dr. Donovan tipped the choice to surgery. Bill went to South Alabama in February 1974. For the five years of his surgical residency, Dr. Lightfoot's mentor and inspiration was Dr. Donovan, from whom he was to hear, "at least a thousand times," the aphorism that has guided him ever since: "A difference, to <u>be</u> a difference, must <u>make</u> a difference."

Although he had originally planned to follow the family tradition and join his father in practice, along the way he developed a strong compulsion to make it on his own. Another factor: he had fallen in love with Mobile. There he has remained since completing his training in 1979, later joined by his younger brother, Robert Dickson Lightfoot, M. D. (His "middle brother" is a Montgomery endodontist, Dr. John Philip Lightfoot.)

His interest in the young physician movement began in a way not affiliated with organized medicine. The Mobile Young Physicians Society was organized as an autonomous group of young

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doctors who might not otherwise have come to know each other in a large city. It was primarily a social organization, where young physicians could share their experiences and common interests.

Dr. Lightfoot was elected President of the group, at about the same time, coincidentally, that the American Medical Association was holding its first meeting for the newly formed Young Physicians Section. He was subsequently invited to a meeting of young doctors at the MASA office in Montgomery. That group elected him to be the Alabama delegate to the AMA Young Physicians' Section. MASA's delegation to the AMA House of Delegates was, he says, very supportive, inviting him to participate in delegation functions.

One thing led to another and, in time, he was appointed to fill an unexpired term on the Board of Censors, at least in part in recognition of his energetic and innovative work with the Young Physicians Section. He was subsequently elected to a full five-year term on the Board and this past April was re-elected to his second term.

Dr. Lightfoot has a quick smile and ready laugh but he's all business at Board meetings. He moves like a shot. Habitually punctual, he rushes about like a man who is always late. This may have something to do with his love of basketball, wherein the mad rush is endemic. It may also have something to do with a deeper meaning in the life of William Malcolm Lightfoot. He is in a hurry.

As a consequence of a profound personal crisis in 1980, he sought — and found — solace and meaning in the spiritual renewal that still dominates his life. Greatly troubled by the collapse of the American family, Dr. Lightfoot believes that nothing less than a national return to values and standards of behavior grounded on religious faith will save the country from what he sees as a downward path to an existence without meaning for ever more millions of Americans.

"I want to see God back in all areas of American life — in Congress, in the schools, everywhere. He has always been in my practice. I could not function without Him. The essential things in my life are these: family, faith, profession, patients, friends. Everything else is relatively unimportant to me."

His spiritual convictions often find their way into his cross-stitching, some of which he gives to friends in appreciation for their understanding, support and love.

The first impression of Bill Lightfoot might be that here is a happy-go-lucky type without a worry in the world. That side of him is genuine, not a pose; but so is the other side, that of a deeply concerned physician, citizen, and True Believer.

Viewed through the prism of modernism, he is perhaps an anachronism, embodying the once solidly American traits of hale-fellow bonhomie and old-fashioned spirituality. (It is not necessary to look beyond the character of the founding fathers, convivial philosophers all, who premised their belief in the simple, pragmatic human right of life, liberty and the pursuit of happiness on the far more complex proposition that these were guaranteed by natural law and "nature's God." They inverted the despised European belief in the divine right of rulers, substituting for it the divine right of the ruled.)

If Dr. Lightfoot had a role model for his beliefs and his intimate involvement in organized medicine it was provided, he believes, by the personal and professional example of William Hollis Cooner, M.D., also of Mobile. Dr. Cooner was a member of the Alabama delegation to the AMA during Dr. Lightfoot's initiation into this phase of his interest, ultimately leading to the present chairmanship of the Board of Censors.

Following are Dr. Lightfoot's answers to questions in a short interview. He was asked to concentrate on areas of greatest concern to him.

"We don't have a health care crisis in this country; we do have an insurance crisis. It troubles me greatly that the approach has been to reinvent the wheel rather than fix a broken spoke.

"My guess is that we will see a watered-down approach to reform this year. Long term, it all depends on how the American public responds. Early on in the debate I was afraid that the public would have no interest whatever, as is so often the case; that there would be a few informed people in Washington and Congress would do its thing, more or less without informed public involvement.

"But I have been gratified to have had many patients asking for more information. From my own observation, they are most concerned about any proposal that will not permit them to pick their doctor, to continue to see the doctor of their choice. And, as you know, Clinton put out information that his plan would let patients choose their doctor, but he neglected to say that the choice would be restricted to the alliance the individual is in. Otherwise, he or she wouldn't have such a choice.

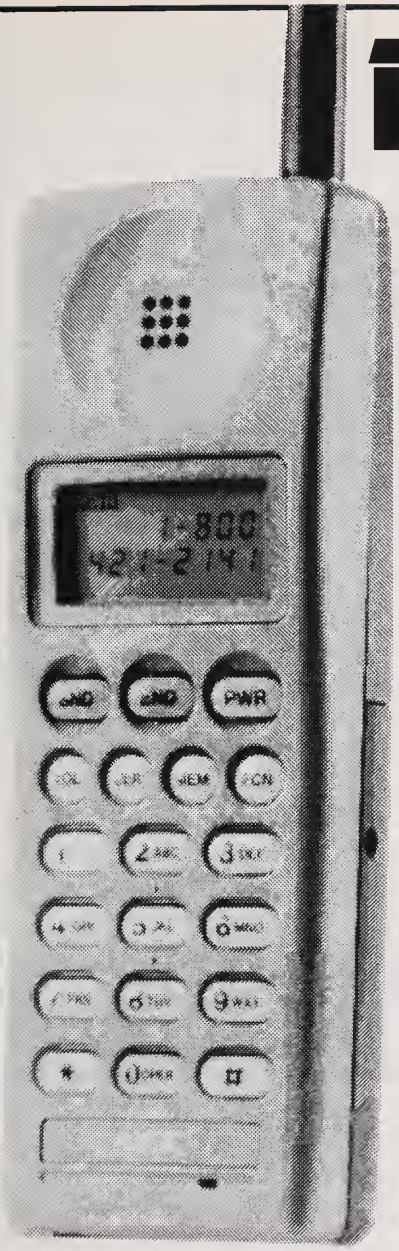
"Another point is one people often overlook: If health care expenditures are capped, there is a limit to the cost-cutting that can be achieved. Then, you will have health care rationing.

"My greatest fear as a physician is that I will live to see the day when I can't do what I know the patient needs done — because they're too old or too sick — and I can't do what is best for them.

"As for the concept of single-payer — it may make some sense superficially, but I have no trust in the federal bureaucracy's ability to run an operation of this magnitude. Once you put all the dollars in one pot, there inevitably arise all the socialistic implications we're all so concerned about.

"Here in the state, I am greatly concerned that there are hundreds of doctors who are not members of MASA. How can we reach them and convince them that what we do is important? They're busy in practice and there is no way they can keep up with what is going to directly affect them in their practice. They must depend on the Association to

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keep them informed. To me anything that affects patient care should be of paramount concern to every physician.

"Also I would like to see more real involvement in organized medicine. Everybody says they don't have the time. But I have discovered that we all make time for what is important to us. If the future of how we deliver care is not important, then I don't know what is.

"Everything we do comes back, one way or another, to patient care.

"The greatest social problem I see, and it also involves medical issues in many ways, is the destruction of the family unit, and how that destruction impacts on where America is heading. We see many aspects of this on the State Committee of Public Health.

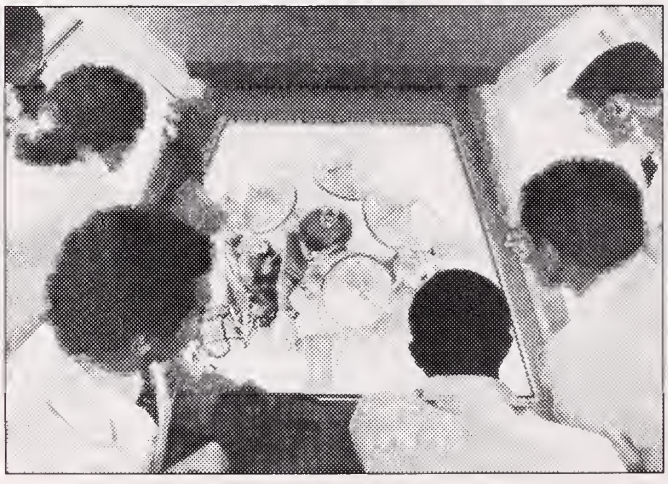
"The Board has been looking at ways physicians can become more involved in the communities of the state. Anywhere we look, the problems of communities derive in great measure from family breakdown. As physicians we see some of the worst results of this breakdown — battered women, abused children — but how can we move from the battlefield-care physician to the preventive-care physician?

"It is an enormous problem, but nothing is more important for society than finding answers.

"Maybe the destruction of the family unit is as big as it is in my mind because I have experienced it, and because I have been doubly blessed — by the family that raised me and the family I am raising [Malcolm, 18; Ross, 8; and Will, 4]. My blessings also include my wife, Daria, who has been very supportive of my work in organized medicine and who has stood by me through thick and thin."

Is there a fifth-generation Dr. Lightfoot in the brood? Time will tell.

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Telemedicine Comes of Age

By Bob Carlson

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It's getting so you can't open a newsmagazine without becoming car-sick. Everybody, from Microsoft CEO Bill Gates to Vice President Al Gore and former Surgeon General C. Everett Koop, seems to have something to say about the information superhighway.

As a media topic, the info highway is almost as ubiquitous as health care. And that's no coincidence. Together, these two megatrends are going to dominate a huge chunk of our future.

Information. Super! Highway?

Information superhighway could be the most overused metaphor of the 90's, along with synonyms such as IT (information technology), I-way, I-bahn (as in Autobahn), or just plain old wired world.

What is it?

According to Microsoft co-founder Paul Allen, what we're talking about is "the marriage of video technology, computer technology, and networking. That's the core convergence of ideas for the information superhighway."[1] Investing $750 million of his Microsoft loot in more than a dozen high-tech companies makes Allen one of the more high-profile developers of products and services for the highway. Some other players with more recognizable names are AT&T, Silicon Graphics, Zenith, the "baby" Bells (Southern Bell, Ameritech, Southwestern Bell, etc.), Apple Computer, Time Warner, Turner Broadcasting, Philips, Intel, CNN, Novell, Microsoft, IBM, Pacific Gas & Electric, Motorola, McCaw Cellular, etc. You get the idea.

The call of the information superhighway is so alluring, and the prospect of being out of the loop so unthinkable, that every state in the Union is busily building its piece of the interstate I-way.

What does it all mean?

It means a networked economy driven by information technology. McLuhan's global village. Videoconferencing. Interactive merchandising. Maybe even virtual reality.

If you're in health care, it means telemedicine.

What is telemedicine?

Not long ago, processing your patients' insurance claims electronically and getting credited electronically was cutting edge. By the broad definition below, it even qualifies as telemedicine. But don't try to impress anyone with that now.

State of the art telemedicine in 1994 means live, full color, two-way video, two-way audio communication, across distances, between health care provider and patient or between health care providers.

In its broadest sense, telemedicine includes the communication of information in the areas of radiology, dermatology, pathology, cardiology, psychiatry, pharmacology, consultation, administration, medical records, billing, research, credentialing, utilization, medical education, and patient education. Telemedicine moves information instead of people.

These definitions, like telemedicine, are evolving. Fast.

According to Ameritech Health Care Marketing Manager Fred Kaiser, health care lags behind other

Telemedicine in Alabama

UAB entered the world of two-way interactive telemedicine last May when a fiberoptic cable went on-line between Kirklin Clinic and Arab-Guntersville Hospital. The UAB site has since been moved to University Hospital, principally because of a better studio, according to Associate Medical Dean William B. Deal, M.D., who oversees physician aspects of the program.

The six-month demonstration project was designed to investigate the usefulness of the audio/visual system in fostering continuing medical education activities and patient consultations between Arab-Guntersville and Birmingham. The project was made possible by DeltaCom and Signal Engineering.

Robert Kristofco, executive director for health affairs continuing education, oversees CME activities during the project. He points out that the system is a logical extension of UAB's pioneering Medical Information Services via Telephone (MIST).

E. Alun Harris, Ph.D., who oversees the technical aspects of the project in the office of the Vice President for Health Affairs, believes that such systems will play an important role in the evolving health care environment.

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industries in terms of investment in telecommunications as a strategic and competitive weapon.

It looks as if health care is about to catch up.

Telemedicine's capabilities.

Right now, telemedicine is being used for diagnosis, medical consultation, CME, patient education, and administration. Soon, it will be used to make electronic house calls. As Dr. Francis Tedesco, President of the Medical College of Georgia, observes, "The limitations will be in our mind, not in the technology."

With telemedicine, almost any diagnostic procedure except palpation can be done remotely. Examination devices are redesigned for telemedicine applications or fitted with appropriate couplers so that a cardiologist can listen to a patient's heart and lung sounds, review the chest X-ray, electrocardiogram, and cardiac ultrasound. An ophthalmologist can look inside the eye. An ENT specialist can examine the interior of ears, nose, and throat. A gastroenterologist can look into the patient's stomach or do a colonoscopy. An orthopedist can do arthroscopy. A pathologist can review a phatology specimen.

"This is all off the shelf technology," says Dr. Jay Sanders, Professor of Medicine and Surgery at the Medical College of Georgia and Director of MCG's Telemedicine Center. "Think of it as a gastroenterologist at a teaching hospital doing a gastroscopy with the fellows and residents watching the procedure on a big TV screen in the room. With telemedicine, instead of being in the room, the TV screen is a thousand miles away."

With the ability to zoom in on an image, telemedicine can actually provide greater detail than direct examination. The tympanic membrane, for example, can fill an entire video monitor.

Two-way audio/video consultation between primary care physician and consulting specialty physician and between primary care physician and patient is experiencing especially rapid growth, according to Fred Kaiser, Health Care Marketing Manager for Ameritech. "They're using it for pre-op and post-op consultation with patients at the Carle Clinic in Illinois."

Telemedicine here and now.

Telemedicine's potential for revitalizing rural health care, for reducing health care costs, and for disease prevention is so enormous, there's not a state in the Union without some sort of telemedicine capability or a telemedicine demonstration project.

An unofficial listing of current telemedicine projects/locations includes Georgia, the Boston Telemedicine Trial, the Columbia Basin Telemedicine Project, the Cuba, N.Y. Telemedicine Project, the Department of Veterans Affairs, the Eastern Montana

Telemedicine is 30-Something.

In The *Telemedicine Handbook*, Dr. Jane Preston traces telemedicine back to 1959, when the University of Nebraska began using two-way, closed-circuit microwave television for medical treatment and education. Dr. Preston herself is a pioneer in telemedicine. She is President of the American Telemedicine Association and formed Telemedical Interactive Consultative Services to manage the Texas Telemedicine Project.

In the late 1950s, STARPAHC (Space Technology Applied to Rural Papago Advanced Health Care), a collaboration between Lockheed, NASA, and the U. S. Public Health Service, began to provide health care to residents of the Papago Indian Reservation in Arizona. The STARPAHC program used a mobile van filled with medical equipment and staffed by two Indian paramedics. Two-way microwave video and audio transmission linked the van to a Public Health Service Hospital and to specialists at another hospital. STARPAHC was dismantled in the late '70s due to budget cuts.

Other early telemedicine applications included an interactive video and audio link between Massachusetts General Hospital in Boston and a medical station at the city's Logan Airport in 1968. The equipment included an electrocardiograph and a stethoscope. The project verified the accuracy of diagnoses made over the video link by a hospital physician with the help of a physician assistant at the airport and also initiated telepsychiatric consultation. Dr. Jay Sanders, now Director of the Telemdicine Center at the Medical College of Georgia, worked with the founder of the Mass General Telemedicine Project, Dr. Kenneth Bird. According to Dr. Sanders, it was Dr. Bird who coined the term telemedicine.

At about the same time, the Interact system at Dartmouth Medical College began to provide specialty consultations and treatment to eight communities in Vermont and New Hampshire. Services included speech therapy for children and continuing medical education. Today, former Surgeon General C. Everett Koop is senior scholar at the Koop Institute at Dartmouth College Medical School. Dr. Koop is an enthusiastic proponent of telemedicine for rural health care, for reducing health care costs, and for encouraging personal wellness and disease prevention.

Telemedicine Project, the Iowa Communications Network, Johns Hopkins University, Mayo Clinic, the Medical Diagnostic Imaging Support System, Oregon Health Sciences University, Pennsylvania Health Net, Texas Tech University MedNet, the Texas Telemedicine Project, the University of Kansas Medical Center, the Greater Dayton Area Health Information Network, the Medical Image Compression Project, Michigan State University/ Kalamazoo Center for Medical Studies, and the Carle Clinic Rural Health Telemedicine Demonstration Project in Illinois.

In Mogadishu, Somalia, the U.S. Army's 86th Evacuation Hospital, in collaboration with Walter Reed Army Medical Center, used telemedicine to provide care for soldiers and civilians. It was called the Operation Restore Hope Remote Clinical Communication System.

Here are case studies from three of these locations, Georgia, Texas, and Montana. Telemedicine practitioners talk about the benefits and the challenges of this revolutionary new health care delivery system.

Hubs and spokes in Georgia.

"Georgia is leading the operational introduction of telemedicine in the United States today," asserts Dr. Jay Sanders. Dr. Sanders is the Director of the Medical College of Georgia Telemedicine Center and Professor of Medicine and Surgery at the College, where he also holds the endowed chair of Eminent Scholar in Telemedicine.

His involvement with telemedicine began 27 years ago when he worked with Dr. Kenneth Bird on the Mass General-Logan Airport telemedicine project. "I recognized his idea was a good one," he says, "even though initially I thought it was crazy." Dr. Sanders ascribes Georgia's success with telemedicine to strong commitments by Governor Zell Miller, the legislature, the President of the Medical College of Georgia, big businesses such as Southern Bell and Georgia Power, and the community into which telemedicine was first placed in 1991. That community was Eastman, about 150 miles from the first hub, the Medical College of Georgia in Augusta. Almost the entire state is now covered with 60 telemedicine sites configured in a hub and spoke pattern.

Georgia's telemedicine network includes two tertiary care academic medical centers and nine community hospitals, with the balance consisting of primary care rural hospitals, primary care clinics and public health facilities. This communication infrastructure allows a patient anywhere in the state to be examined by a physician anywhere in the state.

Deploying the system at a new location goes something like this. First, there is a site visit and meetings with hospital administration and staff to determine needs. The system has an open architecture and is adapted to the end users' needs, not to what the equipment suppliers want to provide. A site survey is conducted and any needed modifications are made. According to Dr. Sanders, the system virtually rolls into the room and is literally plugged into the state communication infrastructure.

"The economics of telemedicine have demonstrated a very interesting situation," says Dr. Sanders. "Telemedicine allows a rural physician to keep a patient in his rural community. The revenue for taking care of the patient stays with that physician and with the rural hospital. And let me point out that increasing the bed census for a rural hospital by a single patient, from 20 patients per day per year to 21 patients per day per year, represents a net cash flow increase of $150,000 per year for that rural hospital administrator." Initial figures indicate that about 85% of the patients who were previously transferred are now being retained in the rural hospital.

"If I put you in a rural hospital bed in Georgia today," Dr. Sanders continues, "your average per day cost is $800. If I transfer you to see a dermatologist at the Medical College of Georgia, your per day cost is $1300, a $500 a day differential. And that does not include the cost of transportation, or your loss of productivity, or the cost of delaying your therapy. So you are increasing the revenue within the rural community and you're decreasing the overall cost to the patient and to whoever is paying the bill." Sanders goes on to note that using telemedicine not only decreases net referrals from rural hospitals, but also increases referrals to the "hub" hospital with telemedicine capabilities.

Because physicians can consult with their colleagues on the network and participate interactively in CME, telemedicine can mitigate the professional isolation many rural physicians feel. Dr. Sanders sees the benefits of videoconferencing flowing the other way, too. "Perhaps as important is getting rid of the professional isolation of the academic physician. If I had to go out into a rural community tomorrow, I wouldn't have the slightest idea how to do that or what kind of patient population I might be dealing with. Yet I'm the one who trains that young physician. So when we talk about professional isolation, there are two sides to that coin."

From the beginning, says Dr. Sanders, he has emphasized that Georgia's telecommunication infrastructure must serve not just telemedicine, but all kinds of advanced communication needs such as business, banking, shopping, and distance education. The two driving forces in building Georgia's I-way, according to Dr. Sanders, are distance learning and telemedicine. The number of distance learning sites in Georgia exceeds 100 and will eventually peak at around 160. This distance learning network will soon be used for interactive preventive health care pro-

gramming between the MCG Department of Pediatrics and K through 12 classrooms throughout the state.

What's next? "We are about to deploy our telemedicine functionality into selected patients' homes," says Sanders. "It's called the electronic house call or the home health care network." Coaxial cable, the kind that brings cable TV into the home, can readily be made bi-directional. Connecting a small video camera to the TV or PC creates an interactive video system. Also connecting instruments like an EKG, an electronic stethoscope, a digital blood pressure cuff, a Doppler, and a pulse oxymeter, makes it possible to assess chronically ill patients on a regular basis without admitting them to a hospital. "When they turn their TV to the electronic house call channel, they're going to be seen and examined by their physician. If we avoid a single hospitalization, that's an average saving of $25,000. If this system works as we think it will, it will change the way we deliver health care in this country."

The Texas Telemedicine Project.

"I grew up in a medical family in the panhandle of Texas. I made rounds with my uncle by car and sometimes we drove up to 150 miles in an afternoon to see patients on their farms. I understand the price of not being able to get to people," says Jane Preston, M.D.

Back in the mid 1950s, when she was on the staff of a hospital in Newfoundland, Dr. Preston recalls setting up a telephone system for diabetic rounds in distant towns which were iced in most of the year. Today, she is the President of the American Telemedicine Association and Director of the Texas Telemedicine Project, headquartered in Austin.

Her interest in telemedicine was triggered by the STARPAHC Project (see sidebar) which provided health care services to a remote Indian Reservation in Arizona and valuable data to NASA for future manned space flight. By the late 1980's, says Dr. Preston, she was reasonably sure telemedicine could be cost-effective if planned properly. "So we looked for the state that had lost the most rural hospitals and it

Rural Indiana, circa 1997.

A family living in rural Indiana is worried about a rash their 11 year old son has had on his body for two days. First, they turn on their TV/PC and ask their family medical network for information. They view a video on common skin disorders in children but still can't figure out what their son has.

They call their local doctor who has their family's health records, but her computer informs them that she is on vacation and won't be back for another four days. The computer asks them which family member is ill and if they need to be put in touch with another doctor. They answer yes and their doctor's computer forwards the son's medical record to the computer of the doctor who is covering while their doctor is on vacation.

This "doctor" is located at the regional hospital and covers for all the area doctors while they are away from their practices through an arrangement with the local hospital. The regional hospital's computer downloads the boy's record into the communications triage department where a trained Emergency Nurse Practitioner (ENP) reviews it and, through the family's interactive TV/PC, asks the family specific questions based on the boy's history.

The ENP is unsure if this may be an allergic reaction to the medication the boy is on or another condition. He captures a video image of the boy's rash and transmits it to the resident on call in the Dermatology Department. The resident compares the image against a library of images on the hospital's training computer and decides that it is a drug reaction. This is communicated to the ENP who, after questioning the family at greater length, decides there is a possibility of anaphylactic shock and that the boy should have epinephrine and cortisone available.

The ENP calls the physician on duty who reviews the case and, after cross-checking for drug interaction problems with the boy's medical record, keys the computer to transmit a prescription to the nearest pharmacy. The pharmacy computer also receives health insurance coverage information and, as the hospital does, either bills the appropriate carrier, debits the correct managed care utilization fund, or debits the medical bank charge card on file for the family. The boy's updated record is then transmitted back to his family physician's computer and the medications are picked up by the family.

At the same time a video on pediatric drug reactions is transmitted to the family and they are given "danger signs" to watch out for. The follow-up department of the hospital is also sent the record summary and a schedule of contacts with the family is entered into their computer. A summary of the case is added to the national drug reaction base for research purposes and the information is also sent on line to the drug manufacturer's data base on product reactions.[1]

1 Adapted from testimony by Brian Heller, Ph.D., Executive Director, Methodist Delivery System, Indianapolis, to the Indiana Utility Regulatory Commission on behalf of Ameritech Indiana filing for Cause 39705. Used with permission.

turned out to be my state, Texas. So we decided it would be good to do it here. The Texas Telemedicine Project was set up to answer a number of questions in a living laboratory, you might say."

Chief among those questions was whether telemedicine could be cost-effective if planned properly. In 1988, she formed a not-for-profit corporation, Telemedical Interactive Consultative Services, Inc. (TICS), to finance, organize, manage and monitor the Texas Telemedicine Project. "I decided to do it without state or federal funds so I could report whatever I found. I was able to raise family foundation money for the management and Southwestern Bell and GTE gave the lines," says Dr. Preston with characteristic understatement.

The Project became operational in 1991. Three sites in Austin – Austin Diagnostic Clinic, Austin State Hospital, and the Texas Youth Commission – provide medical and psychiatric services to four institutions in Giddings, a small town 65 miles away. Lee Memorial Hospital, Lee County Mental Health Clinic, Giddings Regional Dialysis Center, and the Giddings State School.

Specialty consultations available on the network include cardiology, rheumatology, neurology, pulmonology, urology, nephrology, allergy, dermatology, and psychiatry. After one year of operation, the numbers showed that the Project could pay for itself in only 2.6 years. "Can Telecommunications Help Solve America's Health Care Problems?", an often-quoted 1992 Arthur D. Little, Inc., study of the Texas Telemedicine Project and other telemedicine initiatives, projected nationwide health care savings of $36 billion.

In 1992, Dr. Preston founded the American Telemedicine Association, which has become, in her words, "something of a voice for telemedicine." The ATA Board of Directors is a virtual Who's Who of telemedicine in America today. Dr. Preston has also written *The Telemedicine Handbook*, an information-packed, clearly organized work in which she shares her comprehensive knowledge of telemedicine (see sidebar).

"The most important thing I can think of is to get some guidance about how to set up a telemedicine network," counsels Dr. Preston. "You can't find out about a network from a point-to-point system. The figures are very misleading."

What about the limitations of telemedicine?

"I think it's very important that doctors follow the same rules they've always followed. In surgery it's expressed as 'don't cut where you can't see.' If you can't understand what's going on, have the patient brought in. Thus far, my observation is that doctors using telemedicine practice the way they always have, with the focus on the patient and the patient problem. I haven't seen any overextending at all," says Dr. Preston.

The Eastern Montana Telemedicine Network.

"I lived in Alaska. I worked up there in a community as a sole provider 650 miles from the nearest hospital or physician for a year. That's where I got my appreciation for what this technology will do," says Jim Reid, PA-C, principal developer and former Director of the Eastern Montana Telemedicine Project (EMTN). He recently left that position to become a full-time telemedicine consultant. The EMTN is based at the Deaconess Medical Center (DMC) in Billings, the largest city in a 500-mile radius, and consists of six sites, one urban and five rural. Four of the rural sites are hospitals and one is a Community Mental Health Center with outpatient services. Each remote facility is staffed by one or more part-time site facilitators.

DMC is a 272-bed tertiary care medical center and operates a number of programs to address the problems of rural health care delivery and to support the primary care providers in its service area. The EMTN was conceived and developed as another outreach program designed to meet the needs of the rural communities DMC serves. This service area includes eastern Montana, northern Wyoming, and the western Dakotas.

After three years of research and development, a six-month trial of the network was initiated in September of 1993 to demonstrate the potential of two-way interactive videoconferencing technology on rural communities. In November of 1993, the network was awarded $483,000 by the REA to continue the trial for another 12 months. Telemedicine services delivered over the EMTN include patient care services during scheduled specialist telemedicine clinics; consultations requested by rural primary care or mental health professionals, including medical, surgical and psychiatric specialties; routine and emergency X-ray interpretation; consultative interpretation of pathology slides, and endoscopies; and consultative interpretation of echocardiograms, electrocardiograms and other medical imaging.

Because Montana does not have a medical school or residency program, there is also the potential to benefit from links between the EMTN and large academic institutions such as the Mayo Clinic, the University of Kansas Medical Center, or the Medical College of Georgia. Any site on the EMTN can be linked with any of these institutions.

In addition to telemedicine, the network provides three other categories of services: mental health consultation, continuing medical and higher education, and community development applications. The latter category includes a variety of businesses and community organizations such as the Lions Club and church groups. The EMTN is the first telemedicine project to

integrate multiple use applications. "The intent is to spread the cost of the network and the operating costs over a broad enough base so that it's cost-effective for individual end users," says Reid.

While a formal evaluation of the EMTN in cooperation with the University of Montana Business and Economic Research Department is still in progress, Reid shared some preliminary impressions.

"In the long term," says Reid, "I think telemedicine will prove to be an effective, safe and cost-saving way to deliver health care services because it's cheaper to provide those services in the rural community. And that is why managed care will drive this technology. The primary care provider, or gatekeeper, stays in control, more services are provided locally, tests are not duplicated, and when a referral is absolutely necessary, it's to the right specialist the first time because the sorting out has already been done by videoconferencing. Overall, you're getting the biggest bang for the buck."

How have rural physicians taken to the EMTN?

"Most physicians are initially quite resistant to it," admits Reid. "Some warm up and some don't. It's a new and very different way of doing things. It's far easier for a rural physician to say 'I don't know. I'm sending you to a specialist.' They're done. Others would much rather continue to be involved in the patient's care and participate in the telemedicine consult. Other rural physicians resist telemedicine because they feel it's an intrusion on their territory by the urban tertiary care center. In fact, a study in Norway has shown that primary care providers who use telemedicine actually become more competent in managing things they used to refer out."

What about patient acceptance?

"Well over 50% indicate that something is missing from the patient-physician visit when it's done by telemedicine," says Reid. "However, 100% of the same respondents indicate that they would rather have another telemedicine visit than have to travel to see the physician. They're able to gauge the payoff real quick. With telemedicine, the patient is always a winner. The patient always saves. For example, Culbertson, which is the smallest community on our network and the furthest away from Billings, is the greatest user of the network. It's real clear that every patient who is seen over the network saves between $400 and $550 every visit in mileage, lodging, meal expenses and lost wages. If our health care system paid for that, this technology would be in place everywhere."

The trials of telemedicine.

"We don't in general cover telemedicine services under Medicare," says Dr. Helen Smits, Deputy Director of the Health Care Financing Administration (HCFA) in Washington, D.C. "Any payment for telemedicine is being made on a demonstration basis pending information to make future decisions about. We do have a variety of demonstrations going to look at whether we ought to pay and under what circumstances and how much."

At this time, according to Dr. Smits, Georgia physicians are receiving reimbursement for telemedicine services "through an arrangement with the Medicare carrier." In the Texas Telemedicine Project, says Dr. Preston, "None of our doctors received any money." In Montana, Jim Reid says Medicare's current policy against reimbursing for telemedicine services is "extremely unfortunate."

Smits says it's hard to say, but that the demonstration phase "usually takes some years with something this different." HCFA is providing funding to evaluate telemedicine demonstrations in a number of states including Georgia, West Virginia, North Carolina, and Iowa. "Rather than us trying to decide or the site trying to decide, you hire an evaluator, you ask someone objective to look at it, to treat it like an experiment and to look at what can be learned from it. Some of that's done by private consulting firms, some by academic health centers," says Dr. Smits.

What sorts of things are evaluated?

"Cost-effectiveness, patient acceptance, whether the quality of the care appears to be at least equal to the care given in more conventional ways. All the things you'd want to know before you'd start getting all your medical care through telemedicine," says Dr. Smits. "I've been very impressed about how enthusiastic doctors have been, particularly in remote rural sites, about telemedicine's ability to provide them with those kinds of support that they just haven't been able to have before."

"I'm looking forward to what they're going to tell me. One of the big issues is how well physicians accept it, how comfortable they feel with it in the long haul," she added. "There are some physicians that are very enthusiastic about telemedicine and we 're looking forward to seeing if that's generalizable."

Opportunity Indiana.

"Opportunity Indiana accelerates the development of an advanced communication system, including fiber optics, for links throughout the state in Ameritech's service areas for hospitals, schools, and major government centers," says Marv Sacks, Director of External Relations for Ameritech Indiana. "From the standpoint that hospitals are going to be one of the first to link up with this infrastructure, it is a tremendous benefit to health care." The Indiana Utility Regulatory Commission approved Ameritech's Opportunity Indiana Plan in early July of this year. The Plan is the

Hoosier version of other Ameritech initiatives such as its Advantage Illinois Plan, which was announced last November. Opportunity Indiana calls for Ameritech to spend $120 million on communications infrastructure within the state, plus another $30 million on training and equipment for schools. According to Sacks, an implementation plan with more details will be ready in October of this year.

"Opportunity Indiana basically brings the information superhighway to Indiana," says Fred Kaiser, Ameritech's Health Care Marketing Manager. While fiber optic transmission lines are the transport medium of choice for applications like telemedicine, "it all depends on what you want to do," according to Kaiser.

Dr. Donald Sugarman of Fort Wayne Radiology Associates, for example, has been using a picture archiving and communications (PACS) system to receive and transmit digital images at Parkview Memorial Hospital in Fort Wayne since 1985. During this time, Parkview has become the hub for a regional electronic teleradiology network including four other hospitals.

St. Vincent Hospital in Indianapolis has been using existing telecommunications infrastructure for videoconferencing, primarily for administrative and consultative purposes. St. Vincent cardiologists have teleconferenced with physicians in Indonesia to determine how effectively 2-D echocardiograms and heart cath films can be relayed using existing technology. "Down the road," says Alan Handt, M.D., Senior Vice President of Medical Affairs, "we envision a system that will enable us to link up real-time not only with other Indiana physicians, but also with hospitals and physicians world-wide to provide diagnostic and treatment support."

How soon can Indiana physicians do telemedicine?

"As soon as they're ready to sign up for the service with Ameritech," says Kaiser. "The systems and the facilities are available to make that happen now. The costs have come down dramatically over the last four to five years and they're continuing to go down. For those who are willing to make the jump into telemedicine, we can help them do that today."

Dr. Ben Harmon has already made the jump.

Capturing market share.

"So I went downtown to Ameritech and talked to some of the technical people in their lab and drew pictures on chalkboards and explained what I do and how I do it. We came up with this idea of using the existing fiber optic network in the city," recalls Dr. Harmon, a radiologist at Methodist Hospital in Indianapolis. About eight months ago, his idea became the city's first interactive, real-time teleultrasound trial project. He hasn't looked back since.

Dr. Harmon specializes in ultrasound, CT and MRI,

Telemedicine Resource Directory

Jane Preston, M.D.
President
The American Telemedical Association
1700 One American Center
600 Congress Avenue
Austin, Texas 78701

Telephone (512) 480-2247

Jay Sanders, M.D.
Director
Medical College of Georgia Telemedicine Center
1120 15th Street, Building EA
Augusta, Georgia 30912-1655

Telephone (706) 721-6616

For information about the "Second Annual Mayo Telemedicine Symposium"
April 6-9, 1995, contact

Eric G. Tangalos, M.D.
Mayo Clinic
200 First Street Southwest
Rochester, Minnesota 55905

Telephone (507) 284-2511

Jim Reid, PA-C
Innovative Medical Communications
P.O. Box 80691
Billings, Montana 59108-0691

Telephone (406) 698-6855

Marv Sacks
Director, External Relations
Ameritech Indiana
220 N. Meridian Street, Room 995
Indianapolis, Indiana 46204

Telephone (317) 265-2567

Valerie Oravetz
United Medical Network
708 S. Third St., Suite 400
Minneapolis, Minnesota 55415

Telephone (612) 330-0990

with a particular interest in ultrasound. The telemedicine link is between Methodist Hospital, where Dr. Harmon is, and the Glendale Metro Health Center, where his patient is, about 15 miles away. Harmon directs the movement of the ultrasound transducer via a two-way audio link with the technologist performing the procedure on the patient.

"I see the same image on my monitor as it is being generated by the ultrasound machine at the same time as the tech sees it at the remote site," says Dr. Harmon. "The advantage of that is that unlike chest X-rays, ultrasound is a very dynamic modality. How things move and where you put the transducer and is the baby moving, is the heart moving, all that information is critical to the study."

Before this trial project, a technologist would videotape the ultrasound at one of the satellite clinics and deliver the tape to Methodist for analysis. After a three-day wait for results, they communicated the results to the patient. "Now I just explain to the patient and the doctor exactly what's going on, as it's going on," says Dr. Harmon.

Another advantage is that it's easy to monitor problem cases. Of the 800 telemedicine procedures he has done so far, treatment has been expedited for several patients with ectopic pregnancies or other severe conditions that would have required admittance to the ER or a stat ultrasound at night. According to Dr. Harmon, that has resulted in definite cost savings.

Dr. Harmon, who admits to having a strong business feel for medicine, says he is very aggressive about what the Methodist radiology group should be doing. "With this technology, I can project myself electronically to other places without having to drive anywhere," he says. "The coverage I give them is equal or sometimes even better than what I do in the hospital. The more cases I can read, the more lives are in my contracts, the more competitive I will be in the new market. This is the way of the future and if you don't watch out, pretty soon I'll have the whole market."

'Mr. Watson, come here.'

Those, by the way, were the first intelligible words spoken by Alexander Graham Bell over another newfangled contraption, the telephone. Imagine, for a moment, having to demonstrate, with carefully collected data, the cost benefits of using the telephone in your practice; the impact of the telephone on the quality of the care you deliver; patient acceptance of the telephone.

But the benefits of the telephone are obvious, you're saying to yourself. Couldn't imagine running my practice without it. Well, telemedicine is nothing more than the marriage of telephone, television, and computer all technology we take for granted.

"Telemedicine is here to stay," says Jim Reid from Montana. "You should investigate it. You should get your hands on it. You should play with it. You should become familiar with it because it's the way you're going to be doing things."

Reid, who lectures widely on telemedicine, likes to quote these words by Marshall McLuhan in his presentations:

"The future masters of technology will have to be lighthearted and intelligent. The machine easily masters the dumb and the grim."

1 "Over the Horizon with Paul Allen, "by David Kirkpatrick in the July 11, 1994 issue of *Fortune*.

Emergency Medicine Opportunities

Mississippi

Parkview Regional Med. Center
Vicksburg, Mississippi
231 Bed Facility
Annual ED Visits: 15,000
Needs: Director, full-time, part-time

Bolivar County Hospital
Cleveland, Mississippi
188 Bed Facility
Annual ED Visits: 14,500
Needs: full-time, part-time

BMH - Union County
New Albany, Mississippi
153 Bed Facility
Annual ED Visits: 19,000
Needs: Director, full-time, part-time

Gilmore Memorial Hospital
Amory, Mississippi
95 Bed Facility
Annual ED Visits: 13,000
Needs: full-time, part-time

King's Daughters' Hospital
Yazoo City, Mississippi
88 Bed Facility
Annual ED Visits: 22,000
Needs: full-time, part-time

Montfort Jones Memorial Hospital
Kosciusko, Mississippi
76 Bed Facility
Annual Ed Visits: 6,000
Needs: part-time

BMH - North Mississippi
Oxford, Mississippi
150 Bed Facility
Annual ED Visits: 15,000
Needs: full-time, part-time

BMH - Booneville
Booneville, Mississippi
121 Bed Facility
Annual ED Visits: 13,000
Needs: full-time, part-time

Alabama

Jackson County Hospital
Scottsboro, Alabama
170 Bed Facility
Annual ED Visits: 16,000
Needs: full-time, part-time

Clay County Hospital
Ashland, Alabama
116 Bed Facility
Annual ED Visits: 6,000
Needs: part-time

Russell Hospital
Alexander City, Alabama
100 Bed Facility
Annual ED Visits: 12,000
Needs: full-time, part-time

Hartselle Medical Center
Hartselle, Alabama
90 Bed Facility
Annual ED Visits: 8,000 - 10,000
Needs: part-time



Please Contact Donna Gutalj at: (800) 874-4053
For Further Informtaion

Fatal *Streptococcus pneumonia* Infection Due to Hyposplenism

*Joseph H. Embry, M.D., J.D.**

Overwhelming, rapidly fatal *Streptococcus pneumoniae* septicemia occurred in three patients with hyposplenia in a six month period in Alabama. In two cases the patients had had splenectomies after automobile accidents. In the third case, the patient was an infant with pulmonary valve stenosis and congenital absence of the spleen. Prevention of septicemia in such patients is discussed.

Etiology

King and Shumacker in 1953 described five cases of fulminant sepsis in infants who had undergone splenectomy for congenital spherocytosis.[1] Diamond in 1969 first used the term "overwhelming postsplenectomy infection" (OPSI) to describe a fulminant bacteremia, which can lead to a rapid death.[2] In the 1970's there were numerous reports of severe infection in adults following splenic removal.[3,4,5] Overwhelming infection can occur in any asplenic patient, although children are at greater risk, especially those under two years of age.[6] This is probably due to the later development of antibodies against encapsulated organisms, which are the type which cause most cases of OPSI.[7] Defective phagocytosis of encapsulated bacteria, especially unopsonized bacteria, is considered to be the most important etiological factor.[8,9] Immunologic deficiencies are also significant, however, including impaired antibody production, predominantly immunoglobulin M (IgM), which is very important in opsonization of encapsulated bacteria.[10] The spleen is the initial site of production of IgM and of the opsonin, tuftsin.[9,11,12] Tuftsin enchances phagocytosis of bacteria by blood polymorphonuclear leukocytes.

Incidence

The incidence of overwhelming postsplenectomy infection (OPSI) is controversial because published estimates vary considerably.[13,14] The true incidence will not be known until a substantial number of such patients are followed throughout their lifetimes.[15] Prospective studies may result in lower mortality rates, due to quicker response to symptoms. The data of Schwartz, et al were derived by application of actuarial methods to a population free of selection bias and with accurate longterm follow up.[16] This study estimated the risk of fulminant infection in the range of 1 case per 500 patient-years of observation. This is much lower than the overall cumulative risk of infection requiring admission to hospital, which was 33% by the end of a ten-year follow up after splenectomy. In childhood, the incidence of fatal OPSI is in the range of 1 per 300 to 350 patient years. The time interval from splenectomy is important. Most admissions for fulminant infections, 80% in young children, occur within the first two years. The risk, however, is lifelong, and there are case reports of OPSI occurring as long as 42 years after a splenectomy.[7]

Diagnosis

The common features of OPSI include a short, nonspecific prodrome, Howell-Jolly bodies in a peripheral blood smear, a cryptic infection with no obvious focus, massive bacteremia, usually with an encapsulated organism, septic shock, often with disseminated intravascular coagulation, marked virulence with 50% to 70% mortality, and death within 24 to 48 hours.[7,10] *S. pneumoniae* is implicated in roughly half the cases. *Haemophilus influenzae, Neisseria meningitidis* and group A streptococcus have been reported in an additional 25% of cases. Less frequent organisms include *Staphylococcus* species, *Pseudomonas* species, and other gram-negative organisms.[7] Bacterial proliferation may be so extreme that bacteria may be seen in buffy-coat preparations of peripheral smears. Recently the fastidious bacterium DF-2 (*Capnocytophaga canimorsus*) has been identified in OPSI following dog bites.[7] The tick borne protozoan organism, *Babesia microti*, has also been reported to cause overwhelming sepsis in asplenic patients.[17]

Case 1

A 45 year old white female physical education teacher developed fever, chills and myalgia the evening prior to admission. She had the same symptoms the next morning when her husband went to work at 8:30 a.m., and when he called to check on her at 11:30 a.m. When he came home at approximately 12:15 p.m. she was

*State Medical Examiner, Alabama Department of Forensic Sciences Birmingham Division.

unresponsive and pulseless. He attempted CPR until an ambulance arrived at 1:15 p.m. On arrival at the local hospital EKG monitor revealed agonal wide complexes with an ET tube in place and good breath sounds. She was cyanotic and mottled with cool extremities. There was brief return of irregular narrow complex tachycardia, thought to be atrial fibrillation. She had an occasional palpable pulse. Cardioversion was attempted but was unsuccessful. She was pronounced dead at 2:24 p.m., October 22, 1993. The presumptive diagnosis was overwhelming sepsis, S/P splenectomy. Her husband agreed to an autopsy.

Past medical history revealed the patient had a splenectomy in another city in Alabama nineteen years earlier, after an automobile accident. She was eight months pregnant at the time. The clinical features of left rib fractures, left pneumothorax, and low hematocrit (27%) brought her to surgery, where a lacerated spleen and ruptured diaphragm were found. Pathological examination revealed a 215 gram, 12 x 10 x 3 cm spleen with three lacerations, none more than 1.5 cm deep, and extensive parenchymal hemorrhage. The patient's husband recalls some warning regarding the possibility of infections, due to absence of the spleen. The fetus was stillborn. Past medical history was otherwise essentially negative.

At autopsy, the findings were: pulmonary edema; visceral congestion; absence of the spleen; and, microscopically, small vessels in several organs conspicuously filled with diplococci. Post-mortem blood culture revealed *Streptococcus pneumoniae.*

Case 2

A 46 year old white housewife was seen in an emergency room at 6:36 p.m. for fever as high as to 105.4 with a severe shaking chill, headache and "hurting all over" all day. Temperature was 101, pulse 80, BP 96/58, WBC 7,600 with 59 segs, 28 bands, 10 lymphocytes, 2 monocytes, and 1 eosinophil, otherwise normal CBC, and a negative Strep screen. She had been exposed to a child with strep throat. She had history of hypotension with systolic pressure below 100. The clinical impression was probable viral syndrome. She was given Tylenol, Lortab and Nubain and released at 8:30 p.m. She was found unresponsive by her husband the next morning. She was seen again in the ER with apneic respirations, pupils fixed at 4-5 mm, tachycardia, very faint carotid pulse and extreme cyanosis. Blood pressure was unobtainable. During attempts to start an I.V., she developed bradycardia with heart rate of 35 and was given Atropine, 2.5 mg, via the ET tube. Within a minute she developed asystole. An intravenous line could never be placed, and, after 20 minutes of chest compressions with no palpable pulse, she was pronounced dead at 8:23 a.m., November 30, 1993. The clinical impression was possible sepsis, possible DIC. It was noted that she had had some form of abdominal surgery in addition to a hysterectomy. Her husband agreed to an autopsy. Past medical history indicated the patient had a splenectomy in a nearby city three years earlier, due to an automobile accident. Hematocrit was 28.4%. A radiograph of the chest revealed left rib fractures and a CT scan of the abdomen revealed possible splenic rupture. At surgery three or four splenic lacerations, which were oozing blood, were noted. Pathological examination revealed a 160 gram, 12.5 x 9.0 x 5.0 cm spleen with a laceration at one end and with hemorrhage in the contiguous parenchyma. She was given Pneumovax and Pro HIBIT vaccines. Past medical history subsequent to the splenectomy was essentially negative.

Autopsy findings were: hemorrhagic necrosis of the adrenal glands; vascular congestion in the lungs and brain; absence of the spleen; and, microscopically, small vessels in several organs conspicuously filled with gram positive diplococci. Postmortem blood cultures revealed *Streptococcus pneumoniae.*

Case 3

A 5 month old white male was seen by a pediatrician May 17 for symptoms of a cold for a week. He had a temperature of 101. His right TM was red and he was given Tylenol and Augmentin. He was restless that night. His father checked on him at 4 a.m. and he seemed to be asleep. At 6:45 a.m. May 18, 1994, he was found unresponsive. At 6:56 a.m. paramedics found him supine with some rigor mortis in the extremities. His parents requested an autopsy.

Past medical history revealed uncomplicated pregnancy, labor and delivery. Moderate pulmonary valve stenosis was diagnosed at 1 week of age. He was asymptomatic. Ventricular size and function appeared normal by 2D echocardiography. The AV and aortic valves were morphologically normal. The pulmonary valve was quite thickened and it domed in systole. By color flow doppler, turbulence was seen in the right ventricular outflow tract, beginning at the level of the pulmonary valve. He was reevaluated at 6 weeks and at 3 months of age and was essentially unchanged.

Autopsy findings revealed a 28 inch, 15 lb infant. The pulmonary valve was 2.5 cm in circumference with rudimentary pulmonary valve cusps. The aortic valve was 2.6 cm in circumference. The heart weighed 42.2 grams. The right ventricle was slightly thickened and the right atrium and right ventricle were slightly dilated. The spleen was absent. There were three spherical accessory spleens, 2.5 cm, 1.5 cm and 0.5 cm in diameter. Massive hemorrhage was in the adrenal glands and disseminated intravascular coagulopathy was seen microscopically in the liver, kidneys and adrenal glands. Postmortem blood cultures revealed *Streptococcus pneumoniae.*

Comments

Patients with hyposplenism should be made aware of the risk of fulminant septicemia and should wear a

Medic Alert bracelet (Medic Alerti 1000 N Palm, Turlock, CA 95380) describing their condition.[7,8] The possibility of hyposplenism should be ruled out in all patients who present with flu-like symptoms. Splenic salvage by splenorrhaphy, partial splenectomy or simple observation should be attempted in patients with splenic injury when appropriate.[10,19,20] Congenital absence of the spleen should be diagnosed in infants with congenital heart disease or partial situs inversus.[10] Prophylactic antibiotics are recommended in patients under two years of age.[7] Vaccines for *S. pneumococcus, H. influenza*, and, possibly, *N. meningitidis* groups

A and C should be administered to patients with hyposplenism.[7] When Howell-Jolly bodies are seen in a peripheral blood smear, the laboratory should notify the patient's physician.[7] Urgent treatment with high dose parenteral antibiotics should be given to patients with hyposplenism and septicemia. Corticosteroids should be given if the Waterhouse-Friderichsen syndrome develops.[10,17]

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The Department of Health and Human Services, Social Security Administration (SSA), Region IV, Atlanta, Georgia, Requires the services of Medical Advisors in the specialty areas of Internal Medicine, Cardiology, Orthopedics, Psychiatry, Psychology and Surgery to review claims/cases of disability determinations for the SSA disability program. The contractor(s) will work under the direction of and receive work assignments from the Government Project Officer, who is located in Atlanta. All work will be performed on site at the Birmingham, Alabama, Disability Review Section Southeastern Program Service Center (DRS-SEPSC). Contractors will not have any contact with the claimant nor clinical responsibility.

Interested parties should submit a written request for the above Request For Proposal (RFP) Number HHS-94-0020, (telephonic requests will not be accepted) to The Department of Health and Human Services, RASC/DAS/Contracting and Procurement Branch, 101 Marietta Tower, Suite 1519, Atlanta, Georgia, 30323, ATTN: Carl Beckner, Contracting Officer. Anticipated release date of the RFP is September 26, 1994. This requirement is a 100% small business set aside acquisition.

Hospital Medical Staff Section
24th Assembly Meeting
December 1-5, 1994
Sheraton Waikiki Hotel
Honolulu, Hawaii

Representation Education and Networking

Send a representative from your hospital medical staff and physician organization to the 1994 Interim American Medical Association Hospital Medical Staff (AMA-HMSS) Assembly Meeting held on December 1-5 in Honolulu. Aside from participating in the development of AMA policy, representatives will have an opportunity to network with colleagues, dialogue with the AMA Board of Trustees, and hear the latest news and information on health system reform.

With a changing health care environment, broader diversity within the physician population, limited resources, and an overriding need for unity of purpose and action by organized medicine, the AMA has undertaken a study of the Federation.

Federation Consortium Study

The study, involving county, state and specialty societies, the AMA, and other related organizations, intends to uncover useful information for developing ways to increase membership, member participation, and advocacy as well as improve communications, medical society performance, and resource utilization.

Project leaders have asked the AMA-HMSS to participate in the process because it effectively represents grassroot physician concerns. Input from each HMSS representative also will be extremely valuable in defining organized medicine in the future.

The 1994 Interim AMA-HMSS Assembly Meeting Education Program will host the Consortium study. Data collected and analyzed will facilitate the following objectives:

- Identify current and future needs, expectations, and preference of physicians and others for organized medicine;
- Explore membership ideas and options;
- Assess how medical societies relate to each other—including ways to be more supportive, avoid duplication of effort, leverage strengths, and better address weaknesses;
- Discover whether there are better tools/technologies that medical societies can use to communicate with one another and their members; and
- Enable medical societies to work smart in a more focused and purposeful way.

Plan to participate in the Federation Consortium on Friday, December 3 from 2:30 to 5:30 pm in Honolulu, Hawaii. Mahalo!

American Medical Association

Physicians dedicated to the health of America

Physician Impairment:
Current Concepts

*Gerald L. Summer, M.D.**

Chemical dependency in physicians is a primary disease characterized by continuing, compulsive use of mood altering substances despite adverse consequences. Alcohol is one of these substances. The experience of impaired physicians programs is that over 95% of alcoholic physicians self administer other mood altering chemicals, especially the benzodiazepines and newer synthetic opiates. Even physicians not known to be chemically dependent or on mood altering drugs are five times as likely as non-physicians to take sedatives and minor tranquilizers without medical supervision.[1] The important point to note is that the alcoholic physician who does not self-administer other mood altering substances is rare, whereas the chemically dependent or poly-drug abusing physician is the usual scenario.

The incidence of impairment in physicians is similar to the incidence in non physicians. However, self-administration of controlled substances may add to the number of impaired physicians. Physicians usually use drugs to feel normal rather than to get high. The progression of the disease is characterized by increasing the dose of alcohol, opiates, or sedative drugs to acquire the desired effect. Tolerance may be so well entrenched that massive doses are taken on a daily basis. At this stage of the disease, the impaired physician during our initial interview may appear to have it all together, but be unable to practice medicine with skill and safety. The harsh reality is that both the chemical abusing physician and the fully developed chemically dependent physician jeopardize patient safety.

The AMA in 1991 suggested that 10-15% of physicians will be impaired as a result of the use of chemicals at some point in their professional careers. State licensing boards have begun to work with impaired physicians committees in individual states in order to promote early identification, evaluation, treatment and monitoring of impaired physicians. The boards and impaired physicians committees are developing improved communication lines to ensure that patient safety is foremost and that the sick physician gets the treatment he/she needs to begin recovery. Through cooperative experience these goals are beginning to be realized.

Impaired physicians programs which have adequate funding and employ full-time physicians as medical directors seem to encourage increasing numbers of early identification and disposition of impaired physicians. The Alabama Impaired Physicians Committee reviewed 136 consecutive referrals for chemical dependency from time of referral to intervention. Sufficient information was obtained on 21% of the referred physicians for an intervention to be done on the day of referral, 51% within seven days of referral, and 80% within thirty days of referral. Information compiled from consecutive referrals from the Oregon Diversion Health Program for Health Professionals from June 1993 to May 1994 revealed 35% of the interventions were done on the day of notification and 95% within seven days of notification.[2] The Pennsylvania Medical Society Physicians' Health Program reviewed at random ten new cases diagnosed with chemical dependency. The average time firm the initial referral day to intervention was 2.5 days, from initial referral day to entering treatment 3.9 days, and the time interval to signing an advocacy contract with the Physicians' Health Program was 39.9 days.[3] Discussing the length of time it takes to deal with complaints, Gerald J. Bechamps, M.D., the president of the Federation of State Medical Boards, noted that, on average, all of the boards throughout the United States took 26.9 weeks to dispose of or dismiss a complaint.[4] The difference in the time required for resolution of referrals can be attributed to the limits of actions placed upon them. Each has a framework of Rules, regulations, political agenda, and funding restraints. The board needs sufficient evidence for prosecution prior to initiating efforts toward resolution of complaints. Impaired physicians programs do not need the same amount of information prior to intervention in the disease process. Because of the perceived legal vulnerability, hospital administrators and physicians are less likely to refer the impaired physicians to a public regulatory agency.

State legislative initiative is necessary to enable impaired physicians programs to be affective in collaboration with regulatory boards to reach the goals of consumer protection and rehabilitation of the sick physician. Impaired physicians programs' policies and procedures need to be established at an appropriate distance firm the regulatory board to avoid the appearance of a disciplinary entity. The program should be assured of immunity from discovery for referral sources. There should be confidentiality of program records as long as patient safety is assured. There should be sufficient

*Medical Director, Physicians Recovery Network, Medical Association of the State of Alabama, Montgomery, Alabama

open communication between impaired physicians programs and regulatory boards so that mutual trust is established. Such actions encourage earlier referrals.

The emerging experience of state impaired physicians programs shows encouraging results. The Missouri Physician Health Program recently reported the results of 75 participants. At present 92% of these participants are compliant with monitoring requirements and are stable in recovery.[5] The New Jersey study citing nine years experience with chemically dependent physicians showed a no relapse rate of 83.3% at two year follow-up.[6] If one relapse episode with reentry into recovery is included, the success rate rose to 97.6%. The Oklahoma program evaluated treatment outcome based on length of initial in-patient treatment experience. Three to four months of initial treatment resulted in an 85% favorable outcome as defined as complete abstinence or a brief relapse without return to an addictive pattern.[7] This time factor of an additional two to three months appears to be needed to repattern behavior and learn new non-chemical coping skills. The Alabama experience and communication with medical directors of impaired physicians programs in Tennessee, Florida, and North Carolina show similar recovery rates.

The reason for a high successful recovery rate in large part is a result of a cooperative relationship between the state regulatory boards, resulting in an effective protocol of monitoring of the recovering physicians. The old concept that relapse is a natural part of the disease process is no longer valid.[8] Current treatment and monitoring mechanisms minimize the incidence of relapse, and if relapse occurs, close monitoring promotes early identification, reevaluation, and re-entry into recovery.

Current concepts are a result of positive experience gained through change. Initially, medical societies took the initiative to develop impaired physicians programs. Many state regulatory boards have begun to work with impaired physicians committees in order to assure that sick physicians get the treatment they need to provide care to patients with skill and safety. Together, organized medicine and regulatory boards understand that it is more cost effective to rehabilitate a sick physician than it is to finance an entirely new one. In May of 1993 the Federation of State Medical Boards' president established an ad hoc committee on physician impairment to evaluate current concepts regarding physician impairment and to develop medical board strategies for the regulation and management of impaired physicians.[9] The committee's effort promotes early identification and assessment, treatment and monitoring of the impaired physician and provides ongoing efforts to promote public safety. Concurrently, the committee's efforts facilitate the impaired physician's return to a healthier, functioning health care resource for the public.

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The Rise of Cyberdoc

Armed with modems and new software, patients are quietly reinventing health care

Newsweek 9/26/94

Like any other cancer patient, Shirley Hayes felt confused and isolated when she was stricken four years ago. After a lifetime of good health, the recently widowed 60-year-old Milwaukee woman found herself home alone, taking noxious hormones, nursing painful wounds from a radical mastectomy and wondering whether her symptoms were typical. "I didn't know anybody who did," she recalls. "I didn't even know what questions to ask." That changed when Hayes joined a University of Wisconsin research project and the organizers set up a personal computer in her house. By linking her to a fledgling network called CHESS (the Comprehensive Health Enhancement Support System), the computer put her in touch with scores of fellow patients and gave her round-the-clock access to a library of medical information. She even got software designed to help patients choose among different treatments. Now healthy and back at work, Hayes recalls her trips through cyberspace as the best medicine she ever had. "With the computer, you can ask questions you'd be too embarrassed to ask a doctor," she says. "And it's there every minute of the day and night. You never feel alone."

While Congress dithers over health-care reform, people like Shirley Hayes are quietly remaking American medicine. Aided by doc-in-a-box software programs and by online databases and support groups, they're managing their own health in ways that were recently unimaginable. The new tools are of course meant to supplement standard medical care, not replace it. But their role in the health system can only grow, for they're improving people's lives even while reducing their medical bills. "The trend was inevitable," says Dr. Roy Schwarz of the American Medical Association. "It's not going to be reversed unless we burn up the globe." Analysts expect the market for consumer medical software to grow from $20 million this year to $500 million in 1996, and it's not hard to see why. Using new programs like *HouseCall* or *Dr. Schueler's Home Medical Advisor*, anyone with a sore eye or a feverish child can quickly gauge the urgency of the problem. Aware of the liability dangers, manufacturers stress that their products are intended as educational tools, not as do-it-yourself diagnostic kits. But the programs do much more than a hardbound health book. To get help from *HouseCall*, you simply select one of 19 symptom categories (eyes/vision, for example) and answer a series of yes-or-no questions (Is the vision clouded in that sore eye? Has the iris changed color?). The program responds with a ranked list of possible diagnoses, and a click of the mouse yields an encyclopedia entry on each one. The program also describes thousands of drugs, tests and procedures, and lets users store personal medical data for quick retrieval.

For dabblers in multimedia, the offerings get more elaborate. The Mayo Clinic Family Health Book CD-ROM goes beyond diseases and treatments to explain anatomy and the life cycle, and it fleshes out its accounts with colorful animation and video clips, Click on "CT scan" and you see one performed. Mayo also has a new Family Pharmacist CD-ROM, which contains entries on 7,600 medications. Besides describing the drugs, their effects and their hazards, the program uses question-and-answer routines to help identify possible over-the-counter remedies for particular conditions. And it generates personal medication profiles to help users avoid bad combinations.

The information in a software program is of course finite, but connect your computer to a modem and the horizon expands forever. Traveling via the Internet or the commercial online services, laypeople can quickly review literature that would take weeks to track down on paper. CompuServe, for example, offers instant access to 8.5 million scientific citations, covering everything from asthma to xenografts, via the PaperChase databases. And may CompuServe subscriber can sign on to MedSig, a bulletin board that doctors and health experts use mainly to converse with each other. When a curious patient posts a question within one of MedSIG's 22 subject areas, a doctor usually replies. But M.D.'s are careful not to say anything online that could be construed as an actual diagnosis. Besides being irresponsible, it could cause hellish liability problems.

The health-care industry isn't blind to all this. As insurance companies, HMOs and managed-care groups see what electronic services can do for their members — and their budgets — some are getting into the act themselves.



Donna Gosney
A-MASA President

Alliance Health Projects

The actions and rhetoric of legislators have jolted medical families into the realization that they must become politically active. We must all become educated constituents in order to inform patients, friends and members of the community about the issues concerning medical reform. In this election year, when there are so many congressional and statewide races, we should get to know the candidates and their views. It is not to late to get involved and active in these races. Over 150 statewide seats are being decided this year. Annie Marie Gormley, AMASA Legislative Chairman, compiled this article to illustrate the many ways Alliance, members can become active.

Are you getting all you can out of your membership in the Alliance, MASA, and AHA? For whatever reasons you joined, if you are not taking advantage of all or most of the programs that are offered you will not fully benefit from your membership.

As medical families we face unique situations and challenges. Days do not seem long enough to accomplish all that is demanded of our time. Medical practice, families, community service, and church all want to monopolize your time. This year politics should have become an important part of our lives.

The AMA, MASA, and Alliance design programs with a variety of needs in mind. They want to provide benefits and services that will keep physicians at the forefront of medicine and help the practice operate efficiently. Let's look at a few of these benefits.

As a member of the AMA, physicians receive a free weekly copy of AMA News. This newspaper provides the latest information on health care, something that you will not get anywhere else. It is hard to find the time to read everything that comes to the office, but this should be at the top of the list. Check to see if your office manager or your spouse will read it for you and clip pertinent articles.

As a member of the AMA and MASA, physicians and their families are entitled to discounts on magazines subscriptions, travel, long-distance calls, and rental cars to name a few. Also important to members are the investment programs, home equity lines of credit, insurance programs and credit cards.

One of the most important benefits is the opportunity to join the finest operated PAC in the country, AMPAC. Having participated in a number of programs they have to offer, I can honestly tell you AMPAC has a reputation "inside the beltway" as being one of the best. Along with supporting pro medicine candidates, AMPAC offers its members many educational opportunities. We are realize that we can no longer sit back and watch the government attempt to control medical practices and compromise patients' rights. AMPAC's campaign management school, constituent skills workshops and seminars provide you with the skills needed to feel comfortable in the political environment. These programs are not just for people interested in running for office. They are designed to help you see where you can fit into our democratic system, whether it is as an educated constituent or a potential candidate. These programs are offered free of charge to members. Your leaders in Alabama have taken advantage of numerous programs in the past year, such as having Mike Dunn, an expert in developing grassroots lobbying skills, Melinda Ferris and Pat Clark, both excellent trainers in political education, public speaking skills, and media relations.

P.O.W.E.R. is the American Medical Association's legislative and political grassroots network. It is

designed to provide AMA members and their families the tools necessary to communicate with their Senators and Representatives on the many issues surrounding the debate on health system reform.

As health care reform looks like it will leave some major policies and decisions to be decided by the states, it is essential that we support Alapac and MASA. Make sure you are a member of Alapac. MASA lobbyists are well respected and have your best interests in mind. They have an excellent track record and give expert advice to the Alapac board on which candidates to support. They are trying to protect the environment for medical practice and should be looked at as partners. MASA's public relations department, headed by Vic McLean, is working hard to get the good word out on physicians. In addition to a community involvement survey they just conducted, Vic has just finished production on an excellent and poignant videotape designed for patient education and health reform. MASA's Governmental Affairs office has an article in the Alabama MD called Rotunda dealing with legislative affairs. In the event of an urgent call to action, they send out the newsletter STAT.

I want you to be proud of being a member of the AMA, MASA and Alliance! These are membership organizations – be an active member. You will not regret it. For more information on all the programs available to you through MASA, contact Emmett Wyatt at MASA (1800-239-6272). For more information on all the programs available through AMA, contact the AMA Member Service Center at 1-800-AMA-3211.

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

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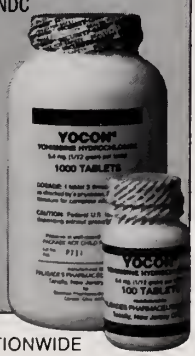
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

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The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

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Final authority on grammar is Webster's *New International*, Unabridged, Second Edition.

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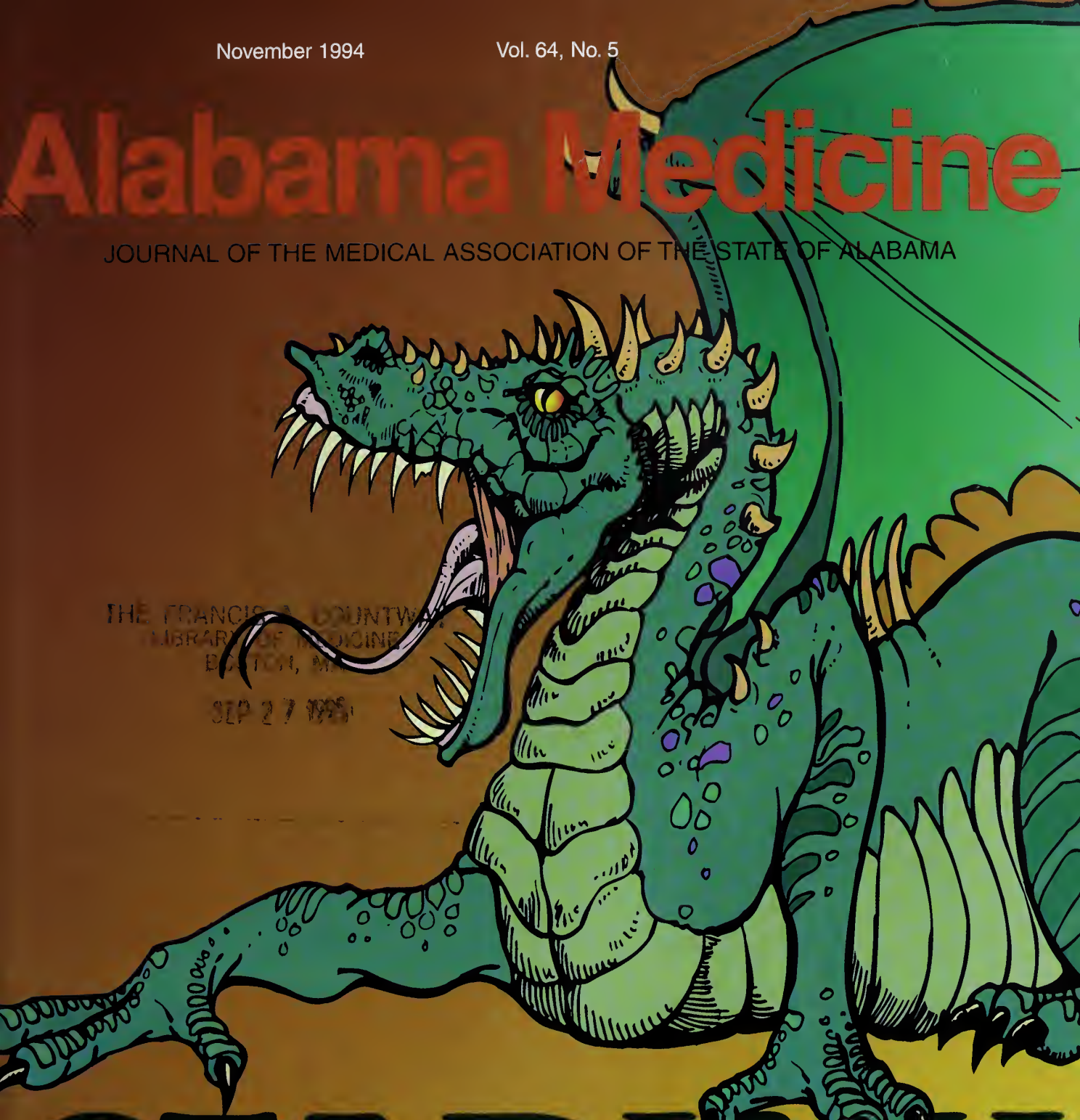
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STARK II

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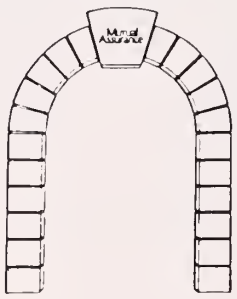
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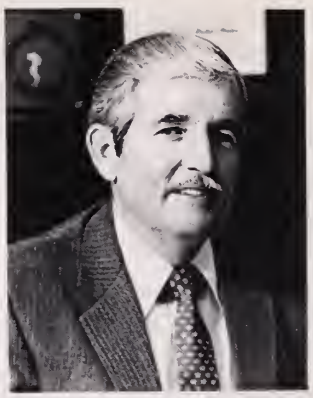
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

A Short History of Elitism

Recent media attention, in Alabama and in other states, has been focused on the structure and performance of those institutions of the medical profession charged with protecting the public from substandard care and errant behavior by physicians.

Actually, the criticisms heard in Alabama and all across the country distort the picture, whether deliberately or inadvertently, by isolating only the most visible point of contact between professional standards and the public interest — where the rubber meets the road, as they say in Washington.

The doctors I serve do not for a moment minimize the importance of this inquiry, but they strongly resent reckless suggestions that organized medicine is just another trade association concerned primarily with group protectionism. Alabama physicians certainly do not think of human life as being a commodity in ordinary commerce, and I don't believe the public does either.

Since honest, able journalists have themselves been tarred with the broad brush of public outrage over the excesses of some elements of their craft — supermarket tabloids and scandal-mongering "infotainment" on television, for example — they should be the last to overgeneralize about the medical profession.

They know, or should know, how even the finest examples of rock-solid integrity in journalism have been besmirched by being lumped with the very worst elements under that unfortunate *omnium gatherum,* "the media."

That being the case, it saddens me to see the willingness of the legitimate, respectable press to leap so quickly from specific examples of alleged system failure to the scattershot insinuation that the house of medicine is indifferent to the public weal.

This is a gross libel. The entire, elaborate structure of medicine, in Alabama, and in the nation at large, was constructed on the granite foundation of patient care, which has evolved over the years, decades and centuries. One way or another, directly or indirectly, patient care is the wellspring from which flow all actions of organized medicine.

From the selection of candidates for medical school on through the watchdog committees in hospitals and the screening of new doctors by the Board of Medical Examiners, *it is a never-ending vigilance that no other group, trade or profession can remotely approach in the constant, unremitting. layered systems of quality control.*

Medicine itself is not an exact science, and never will be. Neither is professional oversight and discipline. Despite the incredible progress in medical science in this century, and most notably in the last half of this century, doctors still can't cure everything. And even the best among them they still make honest mistakes.

Given the complexity of the human body, and the infinite resourcefulness of disease processes in outwitting the most advanced medical science in the world, the physicians of the 21st century won't be perfect either.

Similarly, medical institutions that have evolved as the parallel universe of medical science have not achieved perfection either. They never will. But they will never cease the constant re-examination and redesign that began before either Christ or Caesar.

I have absolute faith in the Board of Censors of MASA. I have closely observed every monthly board meeting since November 1976 – well over 200 meetings and 1,000 hours of deliberations on an infinite variety of patient-care subjects. Never, in all that time, has there been a single question the board did not resolve in a manner consistent with this care as the *first* consideration.

No member of the Board could have been elected by his or her peers unless he or she had an unquestioned dedication to patient advocacy. That is and has

always been the *sine qua non* of service on the Board.

In a country grown terminally cynical toward all institutions, a process accelerated by attack-dog national journalism, this may be greeted with the usual snickers of incredulity. No matter; I know it to be the truth, and that's all that really matters to me. No other profession is so effectively and perpetually governed by such a long and honorable tradition. It works.

In writing this, I know that tradition is also considered as out of fashion as high-button shoes. It is nevertheless alive and well in medicine, and every Alabamian, every American, is a beneficiary of that tradition.

Following is a short history of MASA that I think underscores this point illustrating both public dedication and a constant process of adaptation to changing times, always faithful to the Association's 19th Century motto, *Nos Etiam Sperarumus Meliora*, the eternal hope for better.

For purposes of this discussion, The Medical Association of the State of Alabama was born in 1873. Although county societies had been functioning well before the Civil War — the Mobile Society, for example, was organized in 1839 — the attempt to establish a viable state association in the 1840s had been hampered by the formidable problems of transportation and communication.

Then the war destroyed these humble beginnings, along with the general devastation in the South. The modern MASA was born during Reconstruction amid outcries from the press of the day that mainstream doctors were "elitists" and "monopolists" interested only in feathering their own nests.

It was a time of rampant charlatanism: from the Tennessee line to the Gulf, public gullibility was shamelessly exploited by steam doctors, herb doctors, horseback "cancer surgeons," and every other conceivable kind of uneducated practitioners preying on human misery. Having a vested interest in the status quo, they fed the flames of criticism of mainstream physicians who formed MASA.

The organizers, led by such men of vision as Mobile's Dr. Jerome Cochran, looked at the medical chaos victimizing Alabamians and were determined to establish professional standards of licensure to protect the public.

Simultaneously, the Association designed and urged creation of a state health department, among the first in the nation. All this was hailed from afar by the American Medical Association as the "incomparable Alabama plan."

But it was not easy. Dr. Cochran was vilified in the press and the legislature for his unwavering determination to create a strong professional association committed to state-of-the-art patient care. These were days of *laissez faire* enterprise in the South and in the nation. The very idea of an exclusive professional organization determining who should dispense health care was seen by many as un-American. And licensure was downright satanic. Anybody ought to be able to follow any trade he chose, critics protested. This is America, they bellowed, not Europe.

But Dr. Cochran was nothing if not bull-headed. He knew what had to be done and he did it. It is said that the heavy gold-headed cane he always carried was intended for intimidation of his detractors as much as for his support.

The first Alabama medical practice act had been passed by candlelight on Christmas Eve 1823, immediately after statehood, but there was no mechanism for controlling the standards and protecting the public for the next 50 years — until Cochran's plan was enacted by the Alabama General Assembly in 1875 and 1877.

Simultaneously, the Assembly authorized a state health department and designated MASA as the State Board of Health. In that capacity it directed the successful attacks on yellow fever, malaria, smallpox and other lethal epidemics. The State Health Department went on to participate notably in the conquest of the childhood killers and cripplers — diphtheria, whooping cough, scarlet fever, polio.

The Act of Feb. 9, 1877, mandated that no one could practice medicine in Alabama without a certificate of qualification from an authorized Board of Medical Examiners. For the time, this was a radical concept.

In the beginning, this responsibility for licensure examination was shared between the county medical societies and the state association. But organization of county societies into effective units for control and discipline was slow and erratic in these difficult post war years. Many candidates passed by local doctors were rejected at the state level because of inadequate training or insufficient examination.

Since the General Assembly had placed on the State Association the responsibility for establishing and enforcing qualifications for practice, eventually became obvious that MASA must assume full, centralized authority. The law was amended in 1907, giving the State Board of Medical Examiners exclusive responsibility for licensure. The Board of Censors was designated for this ex officio function.

But frustration remained, in Alabama and in other states. Medical education was itself unregulated and of uneven quality, varying from the superb to a sick joke. Dr. Cochran, who had earlier become so disenchanted with his own M.D. degree that he returned to a different medical college for a second one, remained a persistent critic of medical education until his death in 1896.

Early in the new century, Dr. Cochran's MASA successors met with medical leaders in other states through the good offices of the American Medical Association, in a movement to improve the quality of medical schools.

The AMA established its Council on Medical Education in 1905, thus joining licensing boards in Alabama and in other states with the Association of American Colleges to create a model program of training and licensing.

The next year, 1906, the Council began publicizing the poor scores made on state licensing exams by can-

didates from weak schools. It also began a comprehensive review of standards in medical schools across the country.

Backing for the reform campaign came from the Carnegie and Rockefeller foundations. In 1909, the Carnegie Foundation for the Advancement of Teaching took over the AMA's survey of Medical Schools and appointed Dr. Abraham Flexner to lead the investigation.

The famous Flexner Report of 1910 was a devastating attack on medical education and standards of competence in medical practice, vindicating Dr. Cochran's ceaseless criticisms in the previous century and his demand that MASA centralize control of medical practice at the state level. Soon the American model for medical education became Johns Hopkins, which had been established in 1893.

By the time of the Flexner Report, the American public had become increasingly educated to the equation of good health with scientific medicine. Of the more than 154 medical schools in the country at the time of the report, fewer than half remained by 1928. Quality improved dramatically, but the charge of elitism was again raised by press and politicians.

Whereas at the turn of the century some storefront medical schools were conferring M.D. degrees on just about anyone with the price of a fancy diploma, when Duke Medical School opened in 1932 there were 3,000 applications for 68 openings.

But the finest health care system in the world was being launched. Elitism would win, but the press and politicians would continue to lambaste the profession from time to time with mutually exclusive complaints — for Olympian, godlike hubris or, contrarily, for being primarily just another Benevolent & Protective Order of Good Old Boys.

Because the Board of Medical Examiners had been serving in the capacity of prosecutor, judge and jury of physicians cited for ethical or legal violations, in 1981 the Legislature created an independent Licensure Commission, appointed by the Governor, Lieutenant Governor and Speaker of the House. It replaced the old Healing Arts Board, which had been under the nominal control of the Secretary of State, the Attorney General and the State Superintendent of Education.

The Medical Association of the State of Alabama has no control over or influence with the Licensure Commission, which is autonomous. Neither does the Board of Medical Examiners. Consequently, I have no apology for any actions taken or not taken by the Commission.

MASA's sole interest in this instance, as in all instances, is to protect the rights of the public and the rights of individual physicians. If legislative changes are needed to improve the present system, I am absolutely confident that the Board of Censors will so recommend, mindful as they always are of the exemplary tradition they serve.

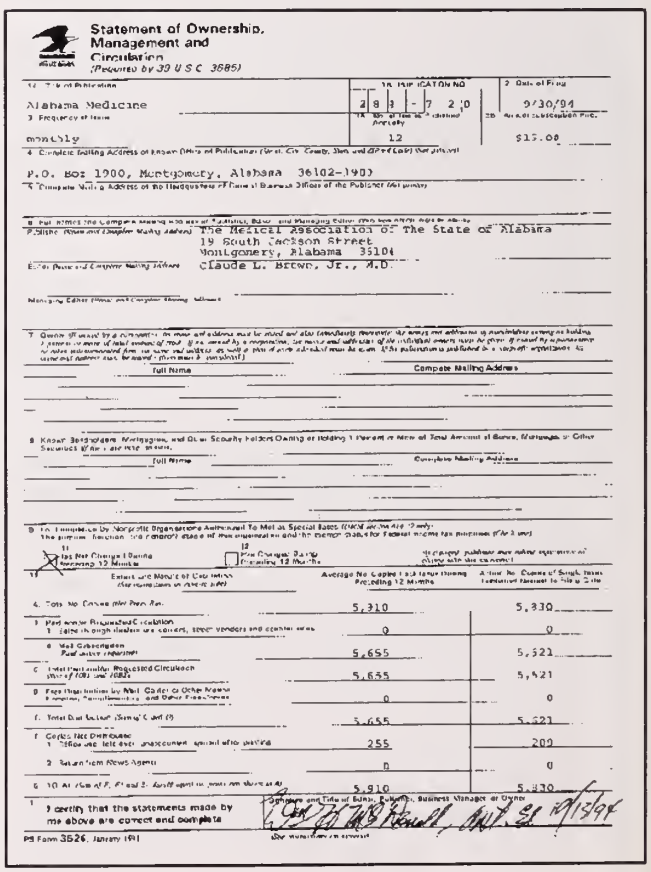
After all, the watchful statue of the formidable Jerome Cochran greets them at the doorway to every Board meeting, adjuring them to keep the faith. I know they will; they always have.

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Now What?

"I predict that before this decade is out, American physicians will be on their knees, at the state and federal level, begging for protection . "

- Uwe Reinhardt, Princeton Health Economist

That giant sighing sound heard across the land came from American physicians expressing relief over the implosion of Clinton-style health care reform. But, as time is reckoned in the rapidly changing landscape of health care, the celebrations may be brief.

The debate over the past 18 months, health economists say, did nothing to alter the underlying conditions that generated the reform effort. Typical of those expressing this opinion was Drew Altman, President of the Kaiser Family Foundation think tank, who responded to the congressional collapse in these words:

"When it comes to health care reform, you can run but you can't hide. The problems that put this on the agenda are going to get worse."

Middle class Americans, who were turned off by what they were told of the reform movement, have not suddenly discovered the solution to their problems, whether of access, affordability, portability, whatever. The choice now, as before, according to the economists, was never between change and the status quo; it was, and is, over who will make the changes, and how, and with what kind of command & control.

Now that the federal government is benched, for a time at least, these economists say, it means only that the system will continue to be rest restructured piecemeal by employers, humongous insurance companies and managed care networks. Now that Congress has opted out for this year, the pressure will grow on the states to provide regulation. Since that avenue is likely to produce confusion and bitter disputes, most experts expect the federal government to be thrust back into the fray sooner or later.

Probably later. The 104th Congress that convenes in January, expected at this writing to be more conservative than the 103rd, will likely be more interested in deficit reduction, such as slashing Medicare /Medicaid, cuts no longer seen as the principal financing mechanism for Clintonomic health care reform. (The President had proposed that we take the money we will not have to spend on Medicare/Medicaid and use that non-money to support his universal coverage plan. This was the most brilliant plan to be offered since the Tennessee legislature decreed that pi [π] would be an even number, to make it easier on school children.)

"The middle class problems that put this on the agenda will only get worse," Mr. Altman says, "as more and more people find their benefits cut, or their choice of physician constrained, or their employers sticking them with more and more of the bill."

Uwe Reinhardt, Princeton health economist, predicts the acceleration of what he sees as a three-tiered trend in the country: poor people and the uninsured treated at public hospitals and clinics; more and more middle class Americans driven into health maintenance organizations and managed care networks; and only the affluent in full choice, fee-for-service medicine.

As Congress gave up the ghost in its long and bitter reform debate, one editorialist commented on the prospects for the country:

"Many Americans, of course, prefer health maintenance organizations and similar health plans, but the change is nevertheless sweeping. And it may seem jarring to a population that has recently heard its rights to choose its own physician passionately — and somewhat surreally – defended by politicians of every stripe. "

There is already a powerful backlash to managed care among doctors, who feel they are at sufferance of cost-conscious health plans, which decide which doctors to carry and which to drop.

"I predict," Professor Reinhardt said, "That before this decade is out, American physicians will be on their knees, at the state and federal level, begging for protection."

He noted that doctor groups are already lobbying hard in state legislatures and in Congress for laws to make it harder for insurance companies and HMOs to exclude physicians from their networks.

Although the rate of increase in medical costs has slowed of late, benefit consulting firms are advising employers that this is a temporary flattening of a curve soon to turn up again, as has happened in the past. Part of the relative calm in medical cost inflation, they are counseling clients, can be attributed to the threat of health care legislation, and some of it to managed care. But actuaries are predicting that employers will be dissatisfied with the rate of increase in health care costs in the future and will continue to seek relief wherever they can find it.

Plainly, Americans didn't want the Clinton plan. But they are still nursing old anxieties, which are expected to re-intensify now that Washington has been sent to the showers: rising premiums, deductibles and/or co-insurance; loss of coverage, either because employers give up and cancel their insurance plans, or because of pre-existing conditions, or because of change of employment.

There is also the highly emotional element that some 8 or 10 million of the uninsured are children, many of whom receive only sporadic treatment, if any at all, for chronic conditions, such as repeated infections, asthma, etc. Apart from the pity they invoke from the general public, they become an even heavier burden on the system as they grow older.

Stuart Altman, a health analyst at Brandeis who has been an observer of reform movements since Nixon days, says of the public mood this year:

"As the debate went on there was a kind of lulling, that the problems weren't so bad.... The press went from pumping up the problems to pumping up the problems of the solutions."

But now, he says, the old problems will return. As giant networks merge and consolidate, buying up hospitals and physician practices; as regimented managed care becomes the norm for the middle class and doctors frantically attempt to preserve their autonomy in an increasingly ruthless market. In a few years, we may well look back on 1993-94 as the good old days.

For my part, I decided long ago that I would simply channel all my concern and energy into taking care of my patients the very best I know how, whatever happens. The green-eyeshade stuff, such as the alarm over the $1 trillion the country is now spending on health care, is something alien to my professional philosophy.

I don't try to comprehend such numbers; I can't relate to them at all and I feel virtually no pressure to try. On those rare occasions when I do feel that I should at least make a powerful effort to understand what the number-crunchers are babbling about, I try to switch my mind to something else, such as The End of Baseball As We Know It, as some other alarmists are still prattling about.

So I really don't have a lot of trouble sticking to my last, which is patient care. But if any of you have problems concentrating on this essential task, it may help to pretend something like this: You are practicing during the London blitz. Bombs are crashing all about you. The block down the street is engulfed in flames. Parliament may be gutted. Litter bearers are bringing new victims into your office every few minutes. The world you knew is disappearing in the smoke. Chaos reigns.

But you don't panic. You remember: it's the RAF's job to worry about Hermann Goering's *Luftwaffe*; it's the Home Secretary's job to attend to damage control in community services; it's the Prime Minister's job to explain it all to the populace. And so on.

Your job is medicine.

Stark II: The Health Care Reform Proposal That Passed

*by Lynda Hendrix, Esq.**

Congress, the President, and the media have all officially declared health care reform dead for 1994. Somehow, however, in the flurry of activity over "real" health care reform, a significant piece of federal legislation, commonly referred to as Stark II, has been forgotten and ignored by many in the government and media. Unfortunately, physicians do not have the luxury of forgetting. The federal physician self-referral legislation that was passed and enacted into law will require physicians to institute their own personal health care reforms prior to the January 1, 1995 effective date of the law to ensure that their medical practices comply with Stark II's mandatory requirements.

Stark II seems to reflect a bias among federal legislators that physicians order medically unnecessary services for their own personal financial gain; therefore, the Stark II self-referral prohibitions are designed to prevent financial benefit if a physician engages in such abusive behaviors. Stark II goes further, however. Instead of allowing market forces to correct the situation or strengthening existing federal enforcement mechanisms already in place to deal with abuses by a minor faction of the physician population, Congress enacted and President Clinton signed into law a statute that is so complex that even experts are unsure of all its intricate details and interpretations.

Complicating and further frustrating compliance with the law is the fact that the regulations implementing Stark II (which ordinarily provide illustrations and more elaboration as to what is meant by the statutory language) are nowhere close to being issued. Nonetheless, compliance with Stark II is mandatory as of January 1, 1995, so this Article will attempt to provide you with an overview of Stark II and what it means for physician practices.

WHEN STARK II APPLIES

Stark II prohibits Medicare and Medicaid reimbursement for any referrals made by a physician to an entity with which the physician has a financial relationship, including both ownership interests and compensation arrangements. If a referral for designated health services is made to an entity with which the physician has a financial relationship, such as a physician ordering an x-ray or lab test within their own group practice, billing Medicare or Medicaid for those services is a violation of the law, unless certain exceptions to the prohibition are met.

Basically a four-part test can be used to determine whether or not Stark II is implicated: (1) Medicare or Medicaid services must be involved; (2) a financial relationship must exist between the physician and the entity being used for the referral; (3) a referral must be made; and (4) a designated health service must be involved.

1. Medicare and Medicaid Services

While at the present time only Medicaid and Medicare reimbursable services are covered by Stark II, an easily determined threshold question, there is a strong momentum in Congress and in many States to expand the scope of this legislation to all payors. A similar expansion in the categories of services classified as designated health services is also anticipated. Therefore, if you must make revisions in your practice in order to comply with the current version of Stark II, try to develop strategies flexible enough to accommodate these expected changes.

2. Financial Relationships

Stark II's definition of a "financial relationship" is extremely broad and, although somewhat vague as to the extent of its reach, is likely to encompass situations where only the slightest hint of remuneration is present. Remuneration under the statute is also very broadly defined to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." Remuneration also includes: (1) forgiveness of amounts owed for inaccurate or mistakenly performed tests or procedures, or correction of minor billing errors; (2) provision of items, devices, or supplies used solely to collect, transport, process, or store specimens for the entity providing the item, device or supply or to order or communicate the results of tests or proce-

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dures for such entity; and (3) payments made by an insurer or self-insured plan reimbursing physicians for claims submitted on a fee-for-service basis, unless the services are rendered pursuant to a contractual arrangement between the physician and the insurer. This last item prevents the creation of prohibited referrals based solely on a physician's status a participating provider under insurance plans.

Financial gain or benefit to the physician is not determinative under this law. A "financial relationship" of any type can trigger the prohibition on referrals, unless the financial relationship that makes a referral prohibited can fit into one of the statutory exceptions. Significantly, the Stark II prohibitions do not extend only to the physician. Hospitals and other health care entities receiving benefits in these situations are also subject to Stark II prohibitions.

The more clearly articulated financial relationship definitions in the statute cover two forms of relationships that physicians are likely to have with health care entities: ownership/investment interests and compensation arrangements. Ownership and investment interests include not only the interests that a physician personally has, but also include any interest an immediate family member of the physician has, thus preventing any transfer of ownership interest to family members as a means of continuing existing, but soon to be prohibited, referral practices.

Unlike the tax code and other similar statutes, Stark II does not set a minimum investment criteria before an ownership or investment interest rises to the level of a "prohibited" financial relationship. Any interest at all is sufficient to invoke the Stark II prohibitions. There is, however, an exception (with seemingly limited applicability) that permits physicians to have ownership and investment interests in regulated investment companies or publicly traded securities having assets or stockholder equity in excess of $75,000,000 on average during the last three fiscal years.

Moreover, the statute does not limit prohibited ownership or investment interests to only those entities directly providing designated health services. A physician's financial relationship with an entity that does not itself provide Stark II designated health services may nonetheless raise prohibited financial relationship issues if the entity the physician has the financial relationship with owns or invests in another entity that does provide designated health services. In such a case, the physician could not refer to either entity nor could either entity bill for services referred by the physician unless the arrangement meets one or more of the Stark II exceptions.

Compensation arrangements under Stark II include traditional salary arrangements existing between employers and employees and personal service agreements, such as independent contractor relationships, or physician recruitment incentives. The legislation targets many other less obvious types of activities as "compensation arrangements." Under the statute, renting/leasing office space or equipment from an entity which the physician refers to is classified as a compensation arrangement, as is the sale of a physician's practice under certain circumstances. Each of these arrangements are the subject of an exception, which will be discussed below. Specifically excluded from the compensation arrangement definition is remuneration a physician receives from a hospital that is unrelated to the provision of designated health services. It is unclear at the present time exactly what activities this provision was designed to protect.

3. Referrals

A financial relationship either through ownership or compensation and a designated health service, however, are not enough to invoke the Stark II prohibitions. A referral must also be involved. A referral occurs when a physician requests a designated health service (such as an x-ray or lab test) for a patient or refers a patient to another health care provider, either for a consultation or for a test or procedure. In addition, if physician compensation in a group practice setting credits the ordering physician's compensation with designated health services ordered by the individual physician, but not personally performed by that physician, these receipts would also be classified as referrals.

4. Designated Health Services

The following services are classified under the statute as "designated health services" that may not be referred, unless an exception to the prohibition can be met:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology or other diagnostic services
- Radiation therapy services
- Durable medical equipment
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

THE EXCEPTIONS TO STARK II PROHIBITIONS

Assuming that all four parts of the test have been met, the designated health services cannot be billed to either Medicare or Medicaid. Stark II does, however, have exceptions to the Medicare and Medicaid billing

prohibition, briefly discussed below.

Group Practices

First, to quality as a group practice, the following tests must be met:

- There must be 2 or more physicians legally organized in some form, such as a P.C. or partnership;
- Physicians in the group must provide substantially the full range of their services within the group practice through the joint use of shared office space, facilities, equipment, and personnel;
- **All physician services by group members must be billed under a billing number assigned to the group** and payments received must be treated as receipts of the group;
- **Overhead and income must be distributed in accordance with pre-determined methods**;
- **Physicians may not be paid, directly or indirectly, based on the volume or value of referrals**, other than in accordance with the special rule governing distribution of profits and productivity bonuses;
- Members of the group must be responsible for performing at least 75% of the patient encounters (in situations where other services may be performed by non-group physicians); and
- The group must meet any other federal regulations issued by the Secretary of Health and Human Services.

Secondly, assuming that the practice meets these tests, in order to bill for ancillary services, the group practice must also meet the in-office ancillary services exception. Durable medical equipment – other than intrusion pumps – and parenteral and enteral nutrients, equipment and supplies are not treated as ancillary services subject to this exception and no other exception exists which would allow a physician to refer and bill for these services. The in-office ancillary services exception applies when services, such as lab and x-ray, are furnished:

- Personally by the referring physician or by a physician who is a member of the same group practice, or personally by individuals who are directly supervised by the physician or by another physician in the group practice;
- In a building in which the referring physician or another member of the group practice furnishes physician services unrelated to the designated health service; or
- In another building which is used by the group practice if the building is used for the provision of some or all of the group's clinical laboratory services or for the centralized provision of the group's designated health services (other than clinical laboratory services); and
- Which are billed by the performing or supervising physician or the group practice of which the physician is a member under billing number assigned to the group or by an entity wholly owned by the physician or group practice. If the ownership or investment interest in such services meets the Secretary of Health and Human Service's requirements.

If the group's compensation formula pays a physician for lab services, x-rays, or other any other in-office ancillary service that is also a designated health service ordered by that physician, the group would not meet the group practice exception. As a result, billing for any ancillary services would be prohibited. If the physician compensation formula does not include paying the physicians for the designated health services ordered by them, the group practice exception would be met, and group profits could be distributed in accordance with the special rule for profits.

Under the profit and productivity bonus special rule for the group practice exception, productivity bonuses may be paid to physicians based on services they personally performed or that are incident to such personally performed services. Furthermore, profits may be distributed based on a share of the overall profit of the group practice so long as the bonus is not determined in a manner which is directly related to the volume or value of referrals.

In order to prevent violations of Stark II, the compensation and bonus structure of the group must be carefully evaluated. If physicians are currently being compensated for ancillary services that are designated health services, payment for those services should not be paid directly to the ordering physician unless that physician personally performed those services. If there is any possibility, however, that ancillary services not personally performed by a physician might be accidently credited to a physician's revenues, a safer choice might be to simply segregate all ancillary services from all physicians' personal production. Once the designated ancillary services are removed from the physicians' personal receipts, paying physicians their own personal production (which does not include ancillary services) is consistent with the statutory requirements.

After the designated health service receipts are segregated from physicians' personal productivity, these receipts could be placed into a separate category. The designated health services receipts could be distributed in various ways and still comply with Stark II. It does not matter how the formula is established as to percentages or allocation, so long as the formula is set in advance and is not based on referrals of designated health services. Instead, distribution might be based

on ownership interest percentages, historical compensation data, or any other criteria unrelated to provision of designated health services.

As noted, the group practice exception requires all billing be done through a billing number assigned to the group. There is currently considerable debate as to what is intended by this statutory language and this has resulted in two very different interpretations. One theory is that a single billing number for the entire entity is required which would mean that all groups, including very large multispecialty clinics, would have to bill all their services through a single provider number. Under the alternate theory, there may be numerous billing numbers assigned to the group as long as the unique physician identification numbers are not used. For instance, in large groups or clinics, each specialty or department could have its own billing number for services rendered by that sector of the practice.

At the present time, contacts at Medicare intermediaries and carriers, as well as HCFA officials, provide conflicting information and are equally unsure as to the proper interpretation of this requirement. Until guidance is received, either through the regulations when they are issued or from administrators and regulators, it is anyone's guess what the actual interpretation will ultimately be. Nonetheless, all physician group practices will need some sort of billing number assigned to the group. Therefore, if your practice does not currently have such a provider number, one should be requested from your Medicare carrier as soon as possible. If the number has been requested in advance of Stark II's effective date, it at least evidences a good faith attempt to comply with this requirement. Larger group practices that may have administrative difficulties with a single billing number may want to obtain written clarification from either HCFA or your carrier as to what procedure must be adopted.

Leasing of Equipment and Space

Provided an equipment or premises lease does not exceed the fair market value for the leased property nor exceed what is reasonable and necessary for the business use of the physician leasing the property, leased equipment and space may fit within a statutory exception if the lease meets a few additional criteria. For both equipment and space leases, the parties sign a written agreement for a least a one year term. The lease amount must be set in advance and not be determined in any manner that takes into account the volume or value of any referrals or other business generated between the parties. The lease must also be commercially reasonable even if the parties made no referrals to each other.

In determining fair market value for office space, a physician or health care entity may not give any value to the proximity of the space to a health care facility, nor may price adjustments be made based on the office's intended use. The law requires that the fair market value be set at the general commercial value for the property, not at what it reasonably rents for as a physician's office.

Employment Relationships

A physician may be the bona fide employee of a hospital or other health care entity and referrals made to that entity will be permitted under Stark II, provided the employment relationship fits the exception. While a written employment contract is not required, the arrangement must be for identifiable services, the salary must be consistent with the fair market value for those services and commercially reasonable, and compensation amounts cannot be related to the volume or value of any referrals made by the physician. Assuming those criteria are met, an employee physician may also be paid a productivity bonus based on services personally performed by the physician.

This bonus allowance does not, however, permit a physician to share in the overall profits of a unit, department, or the entity as a whole. Instead, the bonus definition appears to apply solely to the *personal production* of the physician receiving the bonus. There is a strange twist in the bonus exception – a physician may be paid a productivity bonus based on services personally performed by an immediate family member of such physician. One can only wonder what the legislative intent behind this aberration was!

Personal Service Arrangements

Personal service arrangements can take many forms, but the ones physicians are most likely to be familiar with are independent contractor and medical director arrangements. If a physician enters into an arrangement of that type, the agreement must be for a minimum of one year, all the services to be performed by the physician must be set out in writing, and the agreement must be signed by both parties. Compensation must be set in advance, must not exceed fair market value for services rendered, and must not be determined based on the volume or value of referrals or business generated between the parties. Physicians entering into personal service arrangements with managed care entities, such as HMOs, may also receive incentive bonuses related to reduction and limiting of services to enrollees, as long as the reductions do not limit medically necessary services. This exception follows the same strange twist that the employee exception did and seems to allow one physician to receive the compensation for services rendered by an immediate family member of the physician.

Physician Recruitment

In order to quality for this exception, a physician must geographically relocate to receive recruitment incentives. In addition, the physician cannot be

required to refer patients to the hospital and cannot be paid, either directly or indirectly, based on the volume or value of any referral made by the recruited physician. Because this exception only covers the recruitment incentive portion of remuneration, a recruited physician would also have to meet the criteria for either the employment exception or the personal services exception.

Isolated Transactions

When physicians sell their practices, typically some portion of the selling price is covered by a promissory note or other form of indebtedness. Under Stark II, any debt owed to the physician would create a financial relationship between the physician and the purchaser owing the debt. As such, the selling physician and the purchasing entity could not cross-refer and bill Medicare and Medicaid unless one of the other Stark II exceptions applied. Further, the statute requires that the selling price be consistent with fair market value and commercially reasonable even if no referrals are made.

This prohibition clearly demonstrates one of Congress' general concerns behind this legislation to limit the financial gain possible by a physician – otherwise there would be no reason for the prohibition. If a physician is retiring and selling, there should be no referrals for Stark II to prevent. Moreover, even in the unlikely event that a physician is selling a practice to another physician and the selling physician remains in practice in the same area, physician to physician referrals for professional services are not a referral under Stark II. There are several scenarios, however, where the isolated transaction exception will further the legislative intent: I) it effectively prevents hospitals from purchasing physician's practices in a "sweetheart" deal and subsequently making physicians employees of the hospital with inflated salaries and benefits as a means of locking up the physician's referral stream; and 2) Stark II's anti-referral prohibitions may force physicians to divest themselves of ownership or investment interests in certain ancillary service entities, and by requiring a "cash only" deal, the potential for overly generous selling prices paid out over an extended period of time, intended to induce continued referrals for the ancillary services, is greatly diminished.

REPORTING REQUIREMENTS

To facilitate enforcement of the physician self-referral prohibitions, certain entities are required to disclose and report physician ownership interests. The entities required to report are:

- Hospitals
- Home Health Agencies
- Skilled Nursing Facilities
- Independent Clinical Laboratories
- Renal Disease Facilities
- Health Maintenance Organizations
- Parenteral and Enteral Suppliers
- Ambulance Service Suppliers
- Diagnostic Imaging Service Entities
- Physical Therapy Service Entities

The following information must be disclosed by the above entities:

- The covered items and services provided by the entity.
- The names and unique physician identification numbers of all physicians with an ownership or investment interest in the entity, or whose immediate relatives have such an ownership or investment interest.
- The identity of each person with an ownership or control interest who:
 - — Has directly or indirectly a 5% or more ownership interest in the entity;
 - — Is the owner of a whole or part interest in any mortgage, deed, note, or other secured obligation, which is equal to or exceeds $25,000 or 5% of the total property and assets of the entity; or
 - — Is a partner, officer or director.
- The identity of each person with an ownership or control interest in any subcontractor in which the entity has, either directly or indirectly, a 5% or more ownership interest.
- The employment of any individual who was previously employed by the Medicare or Medicaid intermediary or carrier in a managerial, accounting, auditing, or other similar capacity.
- The name of any person who:
 - — Has a direct or indirect ownership or control interest of 5% or more in the entity, or is an officer, director, agent, or managing employee of the entity; and
 - — Has been convicted of a criminal offense related to involvement in the Medicare, Medicaid, or Social Service programs.

Failure to comply with the reporting requirements listed above subjects the violator to a penalty of not more than $10,000 per day for each day the report is overdue.

PENALTIES FOR VIOLATING STARK II

Penalties for violating Stark II include: i) denial of payment for Medicare and Medicaid claims; ii) requir-



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ing refunds of claims paid in violation of Stark II; iii) monetary penalties of up to $15,000 for each service billed in violation if the physician knew or should have known that the billing was impermissible, and up to $100,000 for each scheme or arrangement entered into whose principal purpose is to assure referrals; and iv) exclusion from participation in the Medicare and Medicaid programs.

While anti-kickback fraud and abuse provisions require "intent" on the part of the provider to establish a violation, Stark II is a mandatory compliance statute. Physicians are expected to comply with the law and to know what the law requires of them, despite the fact that the regulations and appropriate guidance from the government here not been provided, and failure to comply in and of itself is proof of a violation of the law.

The Health Care Financing Administration (HCFA) is so serious on this point that they have proposed sending all Medicare and Medicaid participating physicians a declaration "survey." Both hospitals and physicians will be required to list all health care providers with whom they have a financial relationship on the survey and agree not to refer patients to those providers for services covered by Stark II. In addition, the "survey," when signed, will be treated as an attestation by physicians of their understanding of the law and its prohibitions. There have been some indications that failure to sign the "survey" may result in non-payment of Medicare and Medicaid claims.

Signing this form may have other unexpected consequences. For example, if a physician submits a Medicare or Medicaid claim for a service rendered in violation of Stark II, a zealous regulator could potentially use the form as a basis for filing criminal false claims charges against the physician as a result of violations of Stark II. While the "survey" is still in draft form and subject to change or being totally rejected, it very well may be sent out and physicians should be aware of its potential ramifications. If you receive a "survey," you may want to consider seeking advice from your attorney prior to signing the form.

CONCLUSION

After digesting all the information provided in this Article, one thing must be crystal clear by now – for many physicians, preparing for the new year and Stark II's implementation will require careful review of the status quo. While this Article only attempts to highlight the law (and is no substitute for individual professional guidance), there can be no question as to the far-reaching impact this legislation will have on the medical community. As 1994 is rapidly coming to a close, it is imperative you seek appropriate guidance from your advisors, both financial and legal. Have your advisors review your compensation and in-office ancillary service arrangements, as well as any agreements that you have signed with other health care entities or providers. Make sure that you disclose to your advisors any ownership or investment interest that may raise Stark II concerns. But, most importantly, do not wait until January 1, 1995 to start the review process. Any claims submitted after that date will subject you to sanctions if your practice is not organized and operated in compliance with the provisions of Stark II.

The contents of this Article are intended for general information purposes only, and you are urged to consult your attorney concerning your own situation on any specific legal questions you may have.

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Supports/Training for Alzheimer's Caregivers

State Department of Mental Health and Mental Retardation

Today, about 52,000 people in Alabama have Alzheimer's disease, compared to about 2,800 who have AIDS. Yet, we continue to read and hear more about AIDS than Alzheimer's disease, because Alzheimer's is a silent epidemic. When it strikes homes, families don't talk about it. Many of them struggle quietly and valiantly in small rural Alabama communities, not quite understanding what is happening to them, or comprehending that their lives can never be the same again, as long as their Alzheimer's patient lives. Many do not understand that their Alzheimer's patient will not recover— that brain cells killed by the disease are not replenished.

Public officials and mental health care leaders in Alabama are committed to helping these families. Through the support of the Governor's Office, the Alabama legislature, and the work of the Joint Legislative Study Committee on Alzheimer's Disease, the Department of Mental Health/Mental Retardation Bureau of Geriatric Psychiatry and other state agencies, major progress has been made in the last several years. Many Alabamians—family caregivers, health care professionals and others—have been educated regarding Alzheimer's disease and its symptoms. They're also learning models of caring for Alzheimer's patients at home and in health care facilities. More than 5,000 Alabamians have received training thanks to resources made available through the Dementia Education and Training Act. More impressive progress is on the horizon.

In the past several years, key health care professionals and administrators have developed a vision for care of elderly Alabamians with Alzheimer's disease and other forms of dementia. That vision involves "low-tech" intervention with special emphasis upon community care options. According to Dr. Richard Powers, director of the Department of Mental Health/Mental Retardation Bureau of Geriatric Psychiatry and the Brain Resource Program at the University of Alabama in Birmingham: "In Alabama, we are working very hard to become the national experts in rural dementia care and public mental health. Our efforts during the past several years have had several primary objectives—working in rural areas to educate primary caregivers and linking family caregivers to existing services.

"While these objectives will continue to be important in the next several years, our new objective will be to develop support services in rural areas where none exist today."

Powers and others eagerly anticipate completion of a state-of the-art geriatric psychiatry facility in Tuscaloosa. Experts expect the 126-bed facility—the first public geriatric psychiatry hospital to be opened in the country—to be the nation's premier geriatric facility. The center will serve as a treatment facility, training program and information resource for the state. It will be named the Mary Starke Harper Geriatric Psychiatry Hospital, after one of Alabama's leading geriatric mental health experts.

"When this facility is completed and operational, Alabamians have good reason to be proud," Dr. Powers said. "In designing this building, every detail was examined to assure maximum freedom and autonomy for severely impaired elderly patients." Every step of the way, knowledgeable people were considering things like showers, day areas, nursing stations—would the design be practical and convenient for patients and staff"?

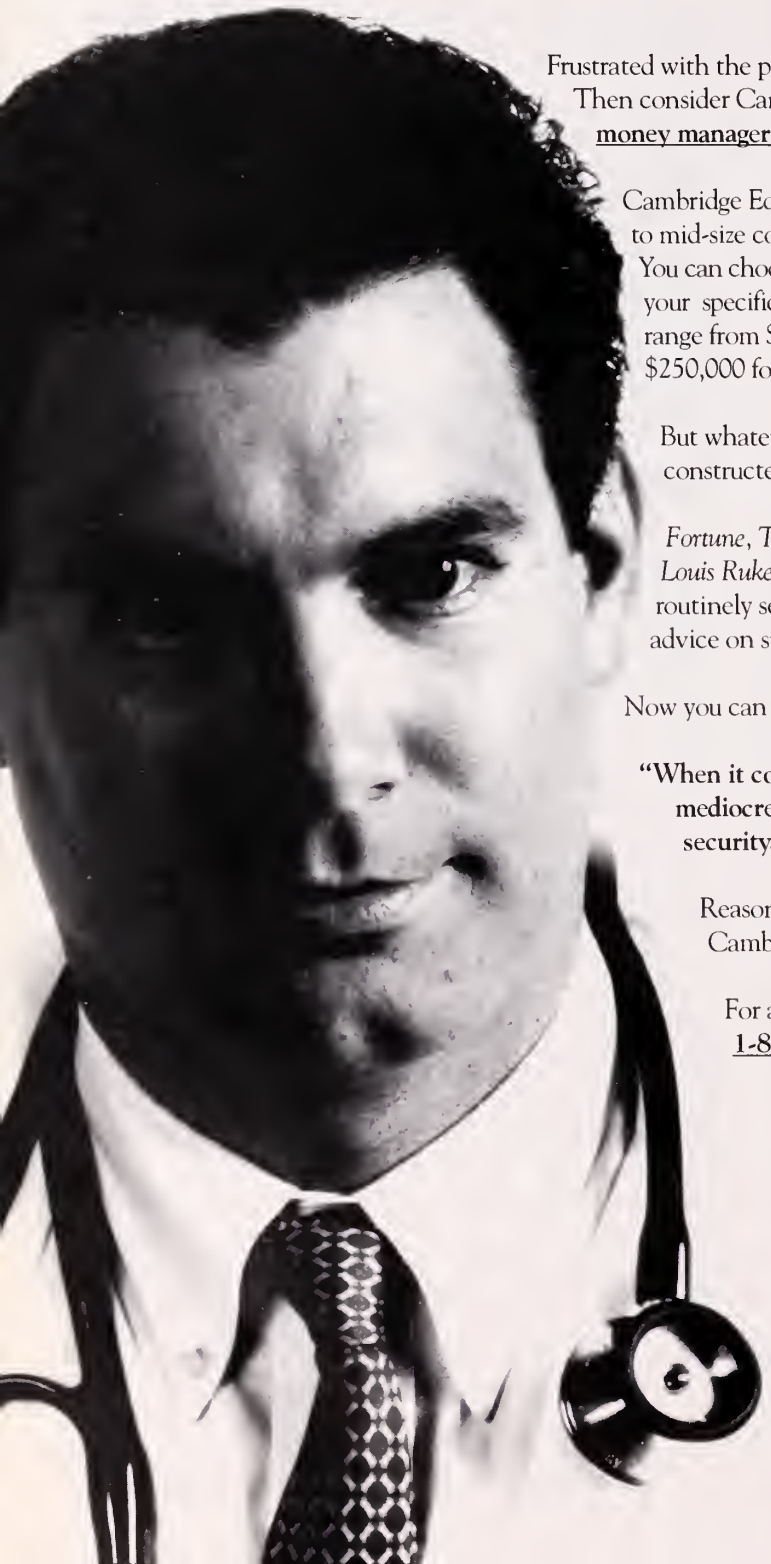
The building is scheduled for completion in the summer of 1995. It will feature separate units for admissions/discharges; extended care for dementia patients; and extended care for chronically mentally ill patients. The center will focus on training nursing personnel, nurse practitioners and other nonphysicians. "It is part of the Department of Mental Health/Mental Retardation's efforts to solve the geriatric mental health care problem that currently exists today," said Richard Hanan, commissioner of the Department of Mental Health/Mental Retardation.

This program includes collaborations with Alabama medical schools and will involve the departments of Medicine and Psychiatry for the College of Community Health Sciences and the Department of Psychiatry in the University of Alabama at Birmingham and the Department of Mental Health. "I see this as a valuable asset to the educational programs of the University of Alabama School of Medicine program at Tuscaloosa," said Dean Roland Fricken, M.D., of the College of Community Health Sciences.

According to Emmett Poundstone, III, associate commissioner for mental illness: "The facility will be only one part of an overall system designed to keep people in their home communities. Other initiatives have been designed to help local caregivers manage Alzheimer's and dementia patients at or near their homes."

Other components of the system will include a statewide toll free Alzheimer information telephone line, staffed by geriatric professionals. Staff will refer callers to services near their homes, answer questions related to Alzheimer's disease or other forms of dementia and refer callers to appropriate sources when their questions relate to legal matters.

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Alabama Physicians Face Managed Care And Powerful Networks

*Thomas P. Weil, Ph.D.**

Will A State Health Services Commission Result?

The meltdown of the Clinton administration health reform plan suggests that managed care, capitated payment, and the regional alliances will serve as the major centerpieces to improve the organization, financing, and delivery of our nation's health services. The reluctance of the American public to embrace either more governmental regulations or more taxes, and with an increasingly conservative Congress, it is doubtful that President Clinton will sign any major health legislation prior to the 1996 election that contains the concepts of employer mandates, universal access, or cost constraints.

What is so significant in any discussions of the efficacy of these emerging health alliances and HMOs for reforming the American health system, is the dearth of evidence available of the potential cost savings or other positive fiscal implications of either establishing networks or by implementing capitated payment.[1] Recent studies lack valid bottom-line estimates of the differences of expenditures among HMO subscribers compared with those enrolled in fee-for-service plans. There is only minimal quantitative evidence now available that the regional alliances can provide a broader range of covered services at a lower cost per subscriber than the more loosely affiliated systems and the indemnity contracts.

These findings lead us to now speculate on the consequences for the medical profession of these ongoing trends and whether the American health system should anticipate by the turn of the century a more procompetitive or a more proregulatory environment. More specifically, some of the potential implications of experiencing four to five major health networks being finally consummated in the Birmingham metropolitan region; one to two each in the Huntsville, Mobile, and Montgomery areas; and, maybe two or three others throughout the state. Roughly 80% of the state's population would thereby be served by physicians and hospitals in the state's seven to fourteen major health networks.

Managed Care is No Panacea

When comparing the ability historically of our HMOs and the regional networks to constrain costs, and the immediate urgency to implement longterm stringent cost containment efforts to reduce our federal entitlements, the managed care concept as the key force to control health expenditures probably should be viewed for a number of reasons as a transitory or temporary solution with a projected window of three- to five-years.

Compared with traditional fee-for-service insurance, HMOs and other managed care plans have achieved only modest results: HMO patients experience somewhat lower inpatient admission rates with slightly shorter average lengths of hospital stay.[2] Those enrolled in managed care plans have the same number or somewhat more physician office visits.[3] As a direct result of the fiscal incentives inherent in capitated payment, HMO members use fewer expensive procedures and examinations.[4] There is somewhat lower satisfaction with HMO services, but this is counterbalanced by the perception that managed care is less expensive than fee-forservice plans.[5] The managed care plans, by micromanaging services, have generally achieved a one-time 7 to 10% overall cost reduction.[6] Although this potential saving must be considered a sizeable amount, it is only equal to roughly one year's inflationary factor of our nation's health expenditures. In comparison, based on the most recent projections, Medicare, Medicaid, and Social Security are currently estimated to consume all federal revenues by the year 2012, unless we raise taxes or reduce benefits or accomplish some of both.[7]

Physicians and other providers as managed care enrollment increases will experience more patients either un- or underinsured, because of the increasing cost of purchasing coverage and the inadequate governmental subsidies provided to the working poor and their dependents. Smaller employer groups will witness the most adverse effects of cost shifting, when Congress enacts further reductions in Medicare and

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Medicaid reimbursement. Concurrently, the managed care plans and the regional networks will continue to experience difficulties in delivering accessible, quality health services to those living in our inner-cities and poor rural areas, where most of those now underserved reside and where there is the most significant shortage of quality providers.[8] To fill that slack, we can expect additional for-profit managed care plans will be organized specifically to collect premiums and to deliver limited care to those in our inner-cities eligible for Medicaid and Medicare.

Managed care plans and regional networks assert that to insure quality care and to lower costs they are forced to establish panels of physicians and hospitals. What is so worrisome is that too many managed care plans and alliances will select low-quality, low-cost providers, whose professional loyalties could be dominated more by the fiscal imperatives of the third-party payers, who assure them of a steady revenue stream, rather than protecting their patient's best interests.

Capitated payment also has the inherent fiscal incentives to encourage a decreased number of services being provided whether it be referrals to specialists and subspecialists; a reduction in the use of expensive procedures and examinations; or, for hospital admissions and patient days. HMO staff at one physician per 800 subscribers compared with one doctor per 415 persons available in the United States suggesting a possible excess of 165,000 physicians by the year 2000.[9] For similar reasons, the average daily census of American hospitals is also projected to decline further. This excess capacity will encourage regional networks to squeeze out many of the area's weakest providers.

While the managed care plans micromanage patient care services and the health alliances establish powerful competitive positions, these organizations will still experience difficulty in decreasing administrative and related overhead expenses. By the United States implementing a multi-payer system with macro- rather than micromanaged controls, we could generate significant fiscal savings. What is preventing us to implement global budgetary targets, as used by other western industrialized nations, is almost everyone unwilling to give government the power to develop health priorities, and to allow public officials to allocate available resources.

As managed care plans implement further cost reductions by constraining the use and the amount of payment for tertiary services, providers in the United States will witness the slowing down in the acquisition of, centralization, and longer queues for patients seeking sophisticated services. Fiscal restraints will force providers to regionalize tertiary care and these sophisticated services will eventually be no longer available to patients in many community hospitals "on demand." Some specialists and subspecialists, as a result, will be reluctantly seeking privileges in nearby teaching centers or otherwise faced with a significant reduction in patient revenues.

Networks Evolve into Regional Monopolies

As more and more physicians are concerned "about being left out," expanded enrollment in managed care plans, capitated payment, and the formation of powerful networks will eventually require that almost all doctors be associated with one of the area's dominant, geographically-linked, vertically and horizontally diversified health alliances. Theoretically, regions that then have excess capacity could significantly reduce their expenditures by closing hospitals or by forcing some of their physicians to relocate to other areas. Faced with a potentially disastrous financial condition, rather than reluctantly "closing their doors," a merger with another larger medical group or being employed by a hospital will often be considered by doctors as a more desirable and feasible option.

These "voluntary" alliances and mergers that are being forged today will often foreshadow the powerful, geographically-linked regional health networks under one corporate umbrella that will be organized as more stringent fiscal constraints require providers to deliver less costly, and more integrated and coordinated services. Almost every hospital in the United States by the turn of the century could be affiliated with one of a maximum of 850 regional networks. A possibly oversimplified calculation by standard metropolitan area (SMA) to illustrate this point follows:

Size of Standard Metropolitan Area	No. in U.S.	Average No. of Networks/ SMA	Total Networks
Under 450,000 persons	221	2	442
450,000 to 1.5 million	72	3.5	252
Over 1.5 million	28	5	140
Total			834

Anticipated to be among the strongest alliances in any region will be those geographically linked; those compatible with existing physician referral patterns; and, those able to develop common culture and goals among trustees, doctors, and various levels of health executives.

In this projected three- to five-year window, additional enrollment in managed care plans and with these alliances gaining additional market share, the result could be one network or in a large metropolitan area several alliances dominating each regional as a virtual monopoly (i.e., an oligopoly). With one large network eventually controlling most standard metropolitan areas in the United States, classical economics has taught us that in a highly competitive marketplace, a goal of an oligopolist is to secure a

monopoly position. The public in contrast could become increasingly incensed about these immense regional health networks as they become too insensitive about access to services, social equity, the comprehensiveness of and quality of care, or particularly its cost.

In consummating a corporate consolidation, merger, or acquisition, a potential hurdle are our federal antitrust laws that reflect a public policy principle whereby free market competition protects consumers, restrains private economic power, and generally produces the best allocation of quality goods and services at the lowest price.[10] Potential anti-trust decrees actually may not be as serious a barrier for these networks to gain common governance as currently perceived by our nation's health leadership. According to a recent (August 1994) U.S. General Accounting Office study, of the 397 acute hospital mergers reviewed by the Department of Justice and the Federal Trade Commission during the 13-year period from the fiscal year 1981 through fiscal year 1993, less than 4% were challenged.[11] Neither the Department of Justice nor the Federal Trade Commission has ever questioned a hospital joint venture. If this trend were to continue, it could be assumed that one or at most a few community care networks will eventually dominate almost all regions nationally.

To protect the public interest from these potential "abuses of Big Business," an earlier idea was to use a state health services commission to allocate a region's capital resources. This concept was proposed in 1959 by the late Ray Brown, who is often considered to be the dean of American hospital administrators.[12] Later on (1970), the American Hospital Association's Ameriplan recommended the formation of a National Health Board to oversee the organization and financing of the United States health system; and, for each state to establish a health services commission to control both the range of services to be offered and set the reimbursement rates for providers.[13] This public utility concept was also the model in the formation (1971) of the Maryland Health Services Cost Review Commission.

Monopolies May Require State Public Utility Regulation

While most physicians, hospitals, insurers, and others in the health industry anticipate that our current market-oriented strategies will generate a more competitive environment, we could instead by the turn of the century, in my opinion, be heading toward this old concept – a public utility model to regulate the health field.

A key question is whether these state health services commissions could integrate and coordinate the competitive – the positive elements of managed care and regional networks – and only implement the needed regulatory provisions so the United States ends up with a more effective and efficient health delivery system. Perhaps an even more fundamental issue surrounding the potential use of the public utility concept for the health field is finding the appropriate balance between the rights of consumers and providers, and governmental control. What is so disconcerting to those of us who support the concept of separation of powers, is that our nation's public utility commissions, when they regulate an industry, merge the powers of the legislative, judicial, and executive branches.[14]

The Achilles heel of the public utility approach, if it was used for the health field, could be the delays that adversely affect the public interest. Delay in the regulatory process could hamper the development of new services and operating efficiencies. Delay could prevent consumers from receiving their share of the benefits flowing from advances in medical sciences and organizational effficiencies. Delay could be costly in terms of human energies expended by the health providers in obtaining approval to make those changes which must be accomplished. These arguments are clearly illustrated by the cost and overall failure nationally of certificate of need (CON) legislation in attempting to control capital expenditures.[15]

What is also of significant concern with the formation of state health services commissions is the regulatory body, not the provider's management, is often responsible for the programmatic and financial success or failure of the organization. As the regulator can often interfere with management's decisions, the commission may discourage entrepreneurial initiates and diminishes the sense of personal responsibility. Or, by providing the privilege of a monopoly to a specific multi-specialty group practice, single-specialty or solo-practitioners in the region may be left at a significant disadvantage.

If all of these defects could be remedied and even if regulation could be made more effective, the performance of these state health services commissions would still fall short, in my opinion, because the difficulties with regulation are largely in the nature of the undertaking itself.

Where Are We Heading?

The American health system is embracing the managed care concept and forming regional networks thereby creating powerful alliances that result in virtual monopolies. To protect the public's interest, these alliances could eventually require regulation by state health services commissions. What is so unexpected is that an aggressive procompetitive environment will ultimately evolve into the need to protect the public's interest by forming quasi-private, quasi-public bodies.

Certainly reintroducing the state health services commission concept is alien to those physicians who visualize that the health reform solution in the United

States is to be implemented almost solely by competitive forces. Some doctors may have never considered that virtual monopolies, as a result of forming these powerful networks and implementing capitated payment, may be in the foreseeable future also require a more regulatory-type ingredient to be located in Montgomery.

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Charles L. Secrest, M.D.
Dr. Secrest received his B.A. degree from the University of Mississippi, and earned his medical degree from the University of Mississippi School of Medicine. He completed his internship and residency in General Surgery at Baylor University Medical Center in Dallas, Texas; served a residency in Urology at the University Medical Center in Jackson, Mississippi; and a fellowship in Adult and Pediatric Reconstructive Urology at Eastern Virginia graduate school of Medicine in Norfolk, Virginia.



James E. Keeton, M.D.
Dr. Keeton received his B.A. degree from the University of Mississippi and his medical degree from the University of Mississippi School of Medicine. He completed his internship and urology residency at University Medical Center, in Jackson, Mississippi. Dr. Keeton served a fellowship in Pediatric Urology *(Senior Registrar)* at the Hospital for Sick Children in London, England; and a fellowship in Urology *(Clinical Assistant)* at the Middlesex Hospital in London.

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Hospital Medical Staff Section
24th Assembly Meeting
December 1-5, 1994
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Representation Education and Networking

Send a representative from your hospital medical staff and physician organization to the 1994 Interim American Medical Association Hospital Medical Staff (AMA-HMSS) Assembly Meeting held on December 1-5 in Honolulu. Aside from participating in the development of AMA policy, representatives will have an opportunity to network with colleagues, dialogue with the AMA Board of Trustees, and hear the latest news and information on health system reform.

With a changing health care environment, broader diversity within the physician population, limited resources, and an overriding need for unity of purpose and action by organized medicine, the AMA has undertaken a study of the Federation.

Federation Consortium Study

The study, involving county, state and specialty societies, the AMA, and other related organizations, intends to uncover useful information for developing ways to increase membership, member participation, and advocacy as well as improve communications, medical society performance, and resource utilization.

Project leaders have asked the AMA-HMSS to participate in the process because it effectively represents grassroot physician concerns. Input from each HMSS representative also will be extremely valuable in defining organized medicine in the future.

The 1994 Interim AMA-HMSS Assembly Meeting Education Program will host the Consortium study. Data collected and analyzed will facilitate the following objectives:

- Identify current and future needs, expectations, and preference of physicians and others for organized medicine;
- Explore membership ideas and options;
- Assess how medical societies relate to each other—including ways to be more supportive, avoid duplication of effort, leverage strengths, and better address weaknesses;
- Discover whether there are better tools/technologies that medical societies can use to communicate with one another and their members; and
- Enable medical societies to work smart in a more focused and purposeful way.

Plan to participate in the Federation Consortium on Friday, December 3 from 2:30 to 5:30 pm in Honolulu, Hawaii. Mahalo!

American Medical Association
Physicians dedicated to the health of America



Donna Gosney
A-MASA President

Domestic Violence

Domestic Violence in the United States has reached epidemic proportion. It has, in fact, been called the disease of the 90s. For years it was said "What goes on in a person's home is private." However, a home is supposed to be a refuge and, for many women, children, and elderly people, it has become a battleground. Kathy MacKay, Health Promotion Chairman for AMA Alliance, says, "The only way to cure domestic violence is to control behavior. The most potent preventive medicine is education, education, education."

Family violence is defined as the use of force with the intent to inflict injury – physical or emotional – against a family member. For victims, the consequences are not always immediate or physical. The emotional and psychiatric problems may seem never ending. The victims of family violence can be children, adolescents, parents, grandparents, men and women.

The potential abusers can be male, female, adolescents or adults. They come from all ethnic, and religious groups. Stress is often a cause of violence. Crises such as losing a job, financial difficulties, marital conflicts, drug or alcohol dependence, illness, or increased dependency of an aging relative can all lead to family violence.

Signs of Family Violence:

Children may have passive or withdrawn behavior; disruptive behavior; neglected appearance; or repeated injuries with unlikely explanations.

In adults repeated injuries; reluctance to spend time with friends or family; increased use of drugs or alcohol; and an obsessive or overly possessive spouse may signal abuse.

The signs among the elderly include frequent bruises, welts, lacerations, or burns; distrustfulness, insecurity, and disorientation. They may also appear dirty, malnourished, and generally neglected.

What can we do about family violence?

Family violence is such an insidious problem that victims feel helpless, alone and totally without support. Since violence is a learned behavior, one which is learned early and repeated as they grow up and have their own families, the danger is even greater. Support for victims of family violence is one way to break the cycle. Programs include community shelters for battered women and their children; women's crisis centers; safe houses for victims of abuse; hotlines with information on where to go for help and counseling centers for victims of family violence.

Educating the public to increase awareness of the problem and the toll it takes on the lives of those involved is another way to address the problem. Alliances can be involved in developing programs to make people aware of the incidence of family violence and ways in which they can be involved in prevention and support; programs for school personnel on detecting the signs of family violence; and programs for children to make them aware of the forms of abuse and violence. The Alliances/Auxiliaries could build a community coalition; establish a violence prevention committee; sponsor a seminar for continuing medical education on family violence; or invite a speaker for a joint meeting of the society and alliance.

The AMAA has these family violence resources available:

AMA Violence Video: a three-minute video featuring clips from children's cartoons, movies, television shows, and media reports that graphically depict why violence in America has reached epidemic proportions.

"Shape Up For Life" brochures on Family Violence and Children Abuse and Neglect. Brochures designed for dissemination at doctors' offices, hospitals, health fairs, and forums.

Campaign Against Family Violence Program Resources: designed to help alliances/auxiliaries address family violence in their communities.

AMA National Coalition of Physicians Against Family Violence: includes treatment guidelines and protocols; information about local contacts, referrals, resources, and model educational programs; and a poster alerting patients of your interest in the concern for this problem. This program is strongly supported by Dr. Robert McAfee. President of the American Medical Association. There is no membership fee.

Whatever the method, promoting awareness of the problem – and what can be done to help the victims – is one very important step in helping a prevent family violence.

This article taken from the "Shape Up For Life," Family Violence, brochure distributed by the American Medical Association Alliance. For information on the materials and programs offered on Family Violence, contact the AMAA, (312) 464-4470.

INFORMATION FOR AUTHORS CONCERNING MANUSCRIPTS

Manuscripts from member physicians should be typewritten, double spaced on white paper 1-1/2 x 11 inches with adequate margins. Two copies should be submitted. Authority for approval of all contributions rests with the Editor. *Alabama Medicine* reserves the right to edit any material submitted. The publishers accept no responsibility for opinions expressed by contributors.

Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month – day of month if weekly – and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

Illustrations: Illustrations should be numbered consecutively and indicated in the text. The number, indication of the top, and the author's name should be attached to the back of each illustration. Legend should be typed, numbered, and attached to each illustration. Photographs should be clear and distinct; drawings should be made in black ink on white paper. For photographs, glossy prints are preferred.

Communications should be addressed by *Alabama Medicine*, The Medical Association of the State of Alabama, P.O. Box 1900, Montgomery, Alabama 36102-1900. Telephone (205) 263-6441, or (toll free in Alabama) 1-800-392-5668.

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December 1994 Vol. 64 No. 6

SPECIAL ISSUE

Alabama Medicine

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA



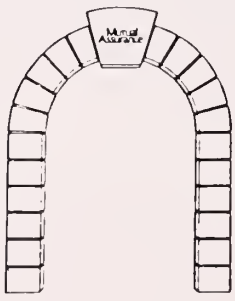
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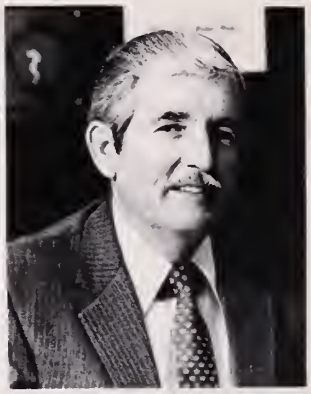
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Dr. Summer's Achievement

This special issue of *Alabama Medicine* is one of the products of a movement that began some 17 years ago, during the 1977-78 term of MASA President John B. McFerrin Rice, Jr., M.D., of Florence. Dr. Rice made the inauguration of a MASA Impaired Physician Program an important element of his presidential year.

The resulting Impaired Physician Committee performed vital service in the ensuing years. Because of my intense interest in the groundbreaking work of the committee, I was honored by being named (1984-87) as the only non-physician on the American Medical Association's Impaired Physician Advisory Committee.

At meetings of that committee, listening to experts in the field and reviewing the literature on the subject, I concluded that as vital as had been the contributions of MASA's committee, an effective program, one that would encompass the whole horizon of physician impairment, demanded a full-time medical director.

In the course of my discussions with other members of the AMA committee, and the authorities brought in to lecture, I noticed that the name of one man came up repeatedly as an ideal choice for Alabama. That name was Gerald L. Summer, M.D., then serving in an assistant capacity in Florida's impaired physician program. He might be available, I learned, because the Florida Legislature had failed to fund the state program sufficiently to enable its director to retain Dr. Summer full-time, which he would have otherwise done without hesitation.

Florida physicians in the field were sold on Dr. Summer. So, as it transpired, was the MASA Board of Censors. Dr. Summer opened his office in the MASA building Oct. 1, 1991.

Although admitting a personal bias, I think it fair to say that Dr. Summer's work in the past three years has been truly outstanding, thrusting him and the MASA program (renamed the Physicians Recovery Network) into the first ranks of impaired physician programs nationally. This issue, written and compiled by Dr. Summer, is further evidence of the reasons for his national stature.

Dr. Summer is one of the most conscientious men I have ever known. He is "mission driven," believing deeply in what he is doing – which is nothing less than salvaging medical lives and families and, at the same time, protecting society.

It is difficult and demanding work, requiring of him the tact of a diplomat and the dogged determination of a traveling salesman. Many adjectives come to mind in describing him – persuasive, energetic, dedicated, thorough, objective, judicious, indefatigable, persistent, tenacious. He is also a heck of a nice guy.

In retrospect, it seems that his whole medical career (he was a practicing cardiologist in West Palm Beach, Florida) was a foreordained trajectory targeting his present calling. And with Dr. Summer, it is a calling, in the classic sense. A recovering physician himself, he is an dedicated student of the genre and a keen analyst of human potential.

This is a vitally important issue of *Alabama Medicine*, addressing as it does what many national authorities believe has already become the impaired physician issue of the 90s. It is a rare physician who does not know of a colleague who may have the kind of problems discussed on the following pages.

I urge your careful study. And if you know of someone PRN can help, contact Dr. Summer. Peer silence can have tragic consequences.

PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

Like Caesar's Wife

I read the other day that the Hubble space telescope has astronomers and cosmologists almost wishing it hadn't been fixed last December by the shuttle astronauts.

Some of the orbiting eye's deep-space findings have thrown into disarray their conventional wisdom about the age of the universe and all that. Scientists analyzing the new data have advised that the universe appears younger than previously thought, and can't be a day over 12 billion years – maybe as young as 8 billion years.

As I understand the quandary, this would make the universe younger by a couple of billion years at least than some stars in our own galaxy, whose age, all concerned seem to agree, is 14 billion years. Obviously, there's a big problem here. If one of the cosmologists were to tell us, "I'm 65 but my left thumb is 67," it would be no more illogical than that a star could be older than the universe that spawned it.

It is my understanding that the new data call into question the big bang theory, and other hypotheses that have not kept me awake many nights. I am sure they will get all this sorted out in due time, pool their new ignorance, and serve up a spanking new model of eternity for all to admire.

The universe, meanwhile, is about the same as it was a year ago, or thousands of years ago. Man has been an inhabitant of that universe for less than a nanosecond of its total history, as cosmic time is reckoned. But in our brief span on the planet, we have learned some universal truths about ourselves, chief among them is that none of us is perfect.

When man moved out of the caves and into what ultimately would be called civilization, he was compelled to accomodate to these imperfections by laws, customs, and codes of ethics, which are constraints on our innate proclivities. In no other human pursuit have these constraints been more restrictive than they are, and should be, in medicine.

Much is asked of those to whom much is given: that is the basic premise of the *noblesse oblige* that has guided medicine and its practitioners down through the centuries. Our manners and morals are held to a much stricter accounting than is the case in other human pursuits.

That is as it should be, for the medical ministry is founded on a sacred trust that finds expression in many laws designed to insulate the doctor-patient relationship against the intrusions and corruptions of the general society.

This issue of *Alabama Medicine* addresses one of the most important aspects of that trust, sexual boundaries in the practice of medicine. They are not new, nor were they new when Hippocrates enunciated them.

Never have the strictures discussed here been more important. We live and practice in a time when public morality has sunken to perhaps the lowest level in the history of the republic. Moral nihilism is the new norm.

When Julius Caesar was asked why he had divorced his wife Pompeia, he explained that she was totally without fault but Plubius Clodius had fallen in love with her: "I would have the chastity of my wife clear even from suspicion."

From this the expression "like Caesar's wife" has survived for two millenia. It describes precisely the conduct expected of physicians – by the public and by their colleagues.

I urge you to read and retain this issue. You may know a colleague who could benefit by the wisdom contained herein.

Professional Sexual Misconduct:

The Current Reality • Current Concepts • Ignorance Is No Excuse

*Gerald L. Summer, M.D.,**
Ellann McCrory, M.D.†

"As the impaired physician was the regulatory issue of the eighties, the problem of sexual intimacies between provider and patients will be the issue of the 90s for most professional regulatory boards."[1]

Physicians were cautioned against professional sexual misconduct as early as the fourth century in the Hippocratic Oath. In contemporary society at least 11 states have passed statutes and imposed criminal penalties for sexual intimacies, and another dozen state legislatures are pondering the passage of such criminal law.[2] Alabama and other state medical boards are developing clear policies and procedures to address those physicians who may be violating the public trust. The practicing physician needs to clearly understand the issues involved surrounding complaints of sexual misconduct.

The Council on Ethical and Judicial Affairs, American Medical Association, has concluded that (1) sexual contact or a romantic relationship concurrent with the physician/patient relationship is unethical; (2) sexual contact or a romantic relationship with a former patient may be unethical under certain circumstances; (3) education on the ethical issues involved in sexual misconduct should be included throughout all levels of medical training; and (4) in the case of sexual misconduct, reporting offending colleagues is especially important.[3]

These conclusions have the potential to cover a whole range of difficulties. They might include the physician who does a physical examination in such a way that the patient feels sexually violated. For example, a patient may come into the physician's office with a complaint of pharyngitis and feel violated as she or he leaves the office after having an unexpected breast or scrotal examination. It might include the family practitioner who sees a patient during an office visit, finds her attractive, and informs her that the patient/doctor relationship is terminated so that they can go out on a date. This scenario implies a romantic or dating relationship concurrent with the doctor/patient relationship and may not be acceptable according to the statement by the AMA Council on Ethical and Judicial Affairs. Any relationship in which a physician risks taking advantage of a patient's emotional or psychological vulnerability would be unethical.

Termination of the physician/patient relationship does not eliminate the possibility that sexual contact between a physician and a former patient may be unethical. The length of the former relationship, the extent to which the patient has confided personal or private information to the physician, the nature of the medical problem, and the degree of emotional dependence that the patient has on the physician – all may contribute to the intimacy of the relationship.[4] The ability of an emotionally involved physician to objectively evaluate these criteria is in question.

What are the sexual misconduct complaints?

Health care providers who engage in sexual misconduct are little different than other educated middle class perpetrators.[5] Their sexual offenses include (1) affairs with vulnerable patients, (2) inappropriate sexual touching through massage or masturbation, (3) inappropriate affectionate behavior (kissing and hugging), (4) unnecessary sexual talk with patients (talking about irrelevant sexual conduct, orgasms, masturbation), (5) exposing the patients, (6) forcible rape of patients, (7) taking pictures of patients for sexual purposes, (8) peeping on patients undressing, (9) utilizing vulnerable patients to gain sexual access to their children, (10) sexual involvement with staff or residents that they supervise.

What are the risk factors for the physician in the physician/patient relationship?

The risk factors include: serious boundary problems; undue physical touch; sensual comments; dual relationships with patients (getting involved recreationally, financially, or romantically); becoming too narcissistic (taking one's importance to patients too seriously); fostering excessive dependence on patients; focusing practice on highly vulnerable clientele; and undue self-disclosure with patients (discussing marriage, family problems, sexual life of the provider, past sexual abuse, financial life). In addition, unusual office practices (practicing when staff are not around, late hours, house calls) and practicing when impaired become problematic.[6]

*Medical Director, Physicians Recovery Network
†Vice-Chairman, Board of Censors, MASA

What is the profile of the patient involved in professional sexual misconduct?

When considering the characteristics of the victim one must be aware that it is not the patient (victim) who should be blamed. Even if the patient is unusually seductive, it is never the patient's fault or responsibility. The physician is the one who has ethical guidelines and must act accordingly regardless of what the patient does. There are several studies showing that childhood sexual abuse victims have higher rates of revictimization as adults, including physician/patient sex, and in many cases, the patient who has been a sexual abuse victim does not understand that sexuality and caring can be distinguished from one another.[7]



Many patients with borderline personality disorders have had sexual abuse histories. Many patients are physically attractive with chronic low self-esteem and have certain other personality characteristics—histrionic, masochistic, dependent personality disorder— and many have a history of numerous psychiatric hospitalizations, suicide attempts, and substance abuse. In many cases this is the treatment refractory patient who often ends up becoming a victim of sexual abuse by the practitioner.

What is the profile of the physician involved in sexual misconduct?

Sexual misconduct is a complex problem involving complex individuals in complex psychodynamic themes. They defy stereotypes. Contrary to old opinion, these "impaired" physicians are often married, religiously affiliated, and professionally competent. They are often narcissistic personalities who are self-absorbed and use people for their own gratification. Female physicians are involved, although male physicians are predominant. Same sex pairings represent a significant problem even though they are less frequently reported than opposite sex pairings.[8] A psychodynamic classification of these individuals is available in the *Bulletin* of the Menninger Clinic which is reprinted with permission in this issue of *Alabama Medicine*.

What is the prevalence of sexual misconduct in the physician/patient relationship?

Of particular interest is the Canadian study reported in 1992,[9] which involved an enormous amount of information from a variety of sources including a large volume of literature on the subject and conducted surveys of the medical profession and public. The survey included all practicing physicians in British Columbia and achieved a response rate of more than 72% (1447 responded). Fifty physicians (3.5% of the 1447 respondents) reported that they had sexual contact with a person who was their patient at the time. This is a smaller number than has been reported in other situations done elsewhere. Ninety-six physicians (84 men and 12 women, 7.3% of the 1447) reported that they had had a sexual contact with someone who was a former patient. Of the 1447 respondents (63.2% of psychiatrists and 20.7% of physicians generally) said they had seen patients who told them of having experienced sexual contact with another physician. It is important to emphasize that this extensive study also concluded that the essence of sexual misconduct between physicians and their patients is exploitative of that relationship. A physician who engages in sexual activity with a patient is putting his or her own wants and needs before the patient's interest and may no longer have the objectivity necessary for professional care.

What sanctions against physicians may occur as a result of professional sexual misconduct?

State licensing boards, ethics committees of professional organizations, malpractice litigation, and civil and criminal statutes all have the potential to impose sanctions. Hospital administrators may initiate punitive action and employers or partners may abruptly terminate the physician. Malpractice suits invariably reach public record and have the potential to be promoted to sensationalism. State licensing boards may impose restriction, suspension or revocation of the physician's license to practice medicine and/or administrative fines. Each of these actions is available to public inquiry and reportable to the National Physician Discipline Data Bank. "As magically as a kiss can transform certain frogs into princes, a hug can change a patient into a plaintiff, a forty dollar motel room can become a one million dollar lawsuit overnight, and a hard-won career can vanish in smoke, never to reappear."[10]

What can a physician do to help his profession and his patient?

Physicians should recognize their own vulnerability.

Any individual, regardless of personal honesty and values, can be vulnerable under certain circumstances. Divorce, separation, loss of a child or spouse, or other times of great personal stress may predispose to breach one's own value system. It has been inferred that many doctors pay much more attention to and think more about their patients than they do their own marriages. A good solid, mutually gratifying marriage is one of the best preventive measures a physician can have.[11]

Following the AMA ethical guidelines, in case of sexual misconduct, offending colleagues should be identified and encouraged to get help. Denial and defensiveness, including minimizing the event, rationalizing and justifying actions, are prominent in inappropriate sexual behavior. "I did it because I have a bad marriage." "I know she was a teenager, but she looked older." "It was her fault—she came on to me." It is unusual for professional sexual misconduct to include only one patient (victim). Furthermore, the identification, evaluation, and treatment of professional misconduct is a narrow specialized field of medicine. The Physicians Recovery Network, the confidential impaired physicians program of MASA, has developed criteria for treatment providers to meet prior to receiving referrals of doctors who have been involved with sexual misconduct for evaluation.

Clinicians tend to feel that they understand the concept of boundaries instinctively, but using it in practice or explaining it to others is challenging. The legal system may implicate any boundary crossing as wrong and harmful even if they do not always constitute malpractice or misconduct. Sexual misconduct usually begins with relatively minor boundary violations.[12] A direct shift from talking to intercourse is rare. The usual scenario is a crescendo pattern of increasing intrusion into the patient's space that culminates in sexual contact. Physicians can avoid the "slippery slope" by following these suggestions:

1) **Do not seek emotional support from patients.** Disclosure of personal marital problems, social or sexual fantasies borders on developing an inappropriate relationship.

2) **Do not ask patients to perform personal services for you.** Avoid giving patients rides home in a car from the office or contact during social events which may tend to give the impression of breaching the physician/patient relationship. Unusual things can happen in cars. See patients in the office during usual office hours with a chaperon present.

3) **Never do an examination on a patient of the opposite sex without a chaperon.**

4) **Recognize your own vulnerability.** Be aware of the profile characteristics of the patient who is predisposed to becoming involved in professional sexual misconduct.

5) **Be careful when exchanging gifts with patients.** Do not be lax about fees nor allow patient debts to go unchecked. Note that the decision to see a patient for free and to discuss that with the patient is quite different from letting the billing lapse or allowing the debt to mount. Within the concept of sexual boundary violations, fact finders may question what type currency you're being paid in.[13]

6) **Exchanging hugs with patients should be allowed cautiously, if at all, within the context of the situation.** Be sure the patient expects it, grants consent, and a chaperon is present. Many physicians may balk at this suggestion, but such precaution is simply prudent.

7) **If a patient is aggressively seductive, in a calm voice simply say:** "This behavior is inappropriate and is not in the best interest of our professional relationship."

The physician/patient relationship is based on trust and the physician is clearly the trustee. Professional standards must be set by the profession itself.[14] The role of the American Medical Association and the Medical Association of the State of Alabama is to educate the profession in regard to these standards.

...I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief; and in particular of sexual relations with both female and male patients.

Hippocratic Oath

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Psychotherapists Who Transgress Sexual Boundaries With Patients*

by Glen O. Gabbard, M.D.

The causes of therapist-patient sex are complex and multidetermined. Efforts to understand why psychotherapists transgress sexual boundaries are hampered by the lure of reductionism and oversimplification. Most of those who examine this issue would prefer to categorize all such therapists as "bad" and "corrupt" as away of distancing themselves and disavowing any similarities between these therapists and themselves. The pathology of therapists who commit sexual boundary violations generally falls into four broad categories: (1) psychotic disorders, (2) predatory psychopathy and paraphilias, (3) lovesickness, and (4) masochistic surrender. Although a variety of individual psychodynamic factors are involved within each group, this classification is highly useful for informed treatment planning.

With sexual misconduct rapidly becoming the number-one liability concern for the mental health professions, the field has been struggling to understand the phenomenon (Apfel & Simon, 1985; Gabbard, 1989; Gartrell, Herman, Olarte, Feldstein, & Localio, 1986; Pope & Bouhoutsos, 1986; Schoener, Milgrom, Gonsiorek, Luepker, & Conroe, 1989). Among these efforts have been several attempts to develop typologies of therapists who transgress sexual boundaries with patients (Averill et al., 1989; Gonsiorek, 1989; Olarte, 1991; Pope & Bouhoutsos, 1986; Twemlow & Gabbard, 1989). A psychodynamic understanding of these therapists and the forces that lead them to resort to such highly self-destructive behavior is more difficult to ascertain.

Part of the difficulty has been a tendency in recent years to politicize therapist patient sex in such a way as to discourage systematic psychodynamic understanding. The "politically correct" view of the phenomenon in some venues is that thoroughly evil male therapists prey on helpless female patients (Gutheil & Gabbard, 1992). In this model, the problem can be solved simply by eradicating the "bad apples" from the profession. This reductionistic view has the appeal of reassuring therapists that those who engage in sexual misconduct are vastly different from them. Therapists involved in this inappropriate activity are a group of "impaired professionals" who can be differentiated from everyone else by their utterly corrupt superegos and their morally reprehensible behavior.

Another aspect of this narrow view of therapist-patient sex is that it lends itself to sexual stereotypes in the culture (Gutheil & Gabbard, 1992). Men are the seducers, and women are the seduced. In one study of sexual transgressions, when female therapists were involved with male patients, the male patients were regarded as responsible and blameworthy for the behavior while the female therapists were viewed as their victims (Averill et al., 1989). Although most studies suggest that males are the perpetrators in the vast majority of cases, substantial evidence now demonstrates that females are also involved in sexual misconduct. Moreover, same-sex pairings represent a significant problem, even though they are less frequently reported than opposite-sex pairings (Benowitz, 1991; Gonsiorek, 1989; Gutheil & Gabbard, 1992; Lyn, 1990).

The fact that sexual misconduct is a complex problem involving a variety of different scenarios becomes apparent to anyone who studies a sufficient number of cases. Systematic examination of data often yields results that do not conform to politically correct formulas. At The Menninger Clinic, where therapists who have transgressed sexual boundaries with patients have been evaluated and treated for many years, this diversity of psychodynamic themes has emerged in the work with these individuals. In this article, I will report on a series of pastoral counselors, social workers, psychiatrists, and psychologists whom I have seen in psychoanalysis, psychotherapy, hospital treatment, or consultation, in addition to other cases in which I have been indirectly involved as a supervisor or consultant to other clinicians. In trying to explicate the psychodynamic themes in these therapists, I have encountered a problem related to confidentiality that

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others in the field have shared. Because I am discussing the psychology of colleagues who may be recognizable to readers of this article, I am not at liberty to describe the details of individual cases. Instead, I am forced for ethical reasons to talk about the psychodynamic themes I have observed in broad brush strokes that paint a general picture but leave out the idiosyncratic and specific details of any one therapist.

A Psychodynamic Classification

It is heuristically useful to group these therapists in rubrics that are psychodynamically based rather than limited to specific diagnostic categories. The vast majority of therapists who become sexually involved with patients will manifest psychopathology that falls into one of four categories: (1) psychotic disorders, (2) predatory psychopathy and paraphilias, (3) lovesickness, and (4) masochistic surrender. The first category, psychotic disorders, is definitely the smallest group, consisting of therapists who suffer from such disorders as bipolar affective disorder, paranoid psychosis, schizophrenia, and psychotic organic brain syndrome. These therapists generally require extensive treatment that includes pharmacotherapy and vocational counseling to discourage them from continuing in the career of psychotherapist. Because the other three categories are more common and more complex from a dynamic perspective, I will consider each of them in substantially more detail.

Predatory Psychopathy and Paraphilias

Within this rubric I am including not only antisocial personality disorders but also severe narcissistic personality disorders with prominent antisocial features. Although all persons suffering from paraphilias are certainly not psychopathic predators, those who act on their paraphiliac impulses with patients under their care generally have a severely compromised superego and character pathology on the narcissistic to antisocial continuum.

These therapists are generally male, but female practitioners have also been reported to fit this category. Benowitz (1991) described two female therapists who engaged in violent behavior during sex with clients, such as urging a patient to perform violent acts with sharp objects on herself. Another female therapist asked a patient to perform the same behaviors that had been degrading to her in past sexually abusive relationships, a common form of sadistic humiliation in this category of therapists. Male offenders in this group tend to have been involved with a long string of clients and are notoriously refractory to rehabilitation of any kind. When caught, they may pretend to be remorseful and claim that they were in love with the patient. They may be masters at manipulating the legal system as well, so they often escape any severe legal or ethical sanctions.

For therapists in this category, patients are regarded merely as objects to be used for their own sexual gratification. Because these therapists lack empathy or concern for the victim, they are incapable of feeling remorse or guilt about any harm they might have done the patient. This massive failure of superego development appears to be related-to profound impairment of internalization during childhood development. The only form of object relatedness they appear to know is sadistic bonding with others through the exercise of destructiveness and power (Meloy, 1988). Some of these therapists have a childhood history of profound neglect or abuse, and some clinicians have understood their exploitation of others as an effort to achieve active mastery of passively experienced trauma (Schwartz, 1992) . One particular variant operating in same-sex dyads involves split-off homoerotic feelings. Therapists who may ordinarily regard themselves as heterosexual may split off and projectively disavow both their own self-loathing and their sexual feelings toward persons of the same sex (Gonsiorek, 1989). They then act out such feelings secretly with their patients, often with cruel and sadistic methods, as a way of compartmentalizing egodystonic homosexual feelings.

Lovesickness

Most therapists who become sexually involved with patients are either predatory or lovesick. In one survey of psychiatrists (Gartrell et al., 1986), 65% of those who had been in a sexual relationship with a patient described themselves as being in love with the patient. Lovesick therapists may be associated with a variety of different diagnostic categories (Gabbard, 1991a; Twemlow & Gabbard, 1989). In some cases, they suffer from less severe forms of narcissistic personality disorder that lack the antisocial features typical of the predatory group. The narcissistic themes in these therapists involve a desperate need for validation by their patients, a hunger to be loved and idealized, and a tendency to use patients to regulate their own self-esteem. Some lovesick therapists may have borderline personality disorder that leads them to quickly idealize patients and impulsively act on their feelings of infatuation. Still others in this category have neurotic problems, while some are essentially normal, from a diagnostic standpoint, but are in the midst of a life crisis.

The most common scenario is that of a middle-aged male therapist who falls in love with a much younger female patient while he is experiencing divorce, separation, disillusionment with his own marriage, or the loss of a significant person in his life (Gabbard, 1991a; Twemlow & Gabbard, 1989). He may begin to share his own problems with his patient and present himself in psychotherapy sessions as needy and vulnerable. This role reversal is a common precursor to sexual

transgressions.

One way of viewing this development in a psychotherapy process is to describe the countertransference as having become erotized in the same way that certain incest victims and borderline patients develop erotized *transference* (Blum, 1973; Gabbard, 1991a). The ability to distinguish a countertransference wish from the reality of the situation is compromised, so that the loving feelings toward the patient lose the "as if" quality characteristic of milder forms of transference. The therapist can no longer appreciate that something from the past is being repeated and that feelings for significant persons from the therapist's past are displaced onto the patient. In light of this loss of insight, a form of "nonpsychotic loss of reality testing" can be observed (Twemlow & Gabbard, 1989, p. 83). Outside the particular *folie à deux* that involves the therapist-patient dyad, the therapist's reality testing appears to be intact. Within the dyad, however a loss of judgment and reality testing makes it difficult for the therapist to see how self-destructive and harmful the relationship has become. Indeed, many lovesick therapists, when confronted, will insist that the relationship transcends any considerations of transference and countertransference.



A variety of psychodynamic themes can be identified in cases of lovesickness. In any single case, one or several of the following issues may figure prominently in the therapist's transgression:

• *Unconscious reenactment of incestuous longings.* There can be little doubt that therapist-patient sex is symbolically incestuous to both therapist and patient. Each member of the dyad is a forbidden object to the other. For the therapist, the psychological proscription is intensified by ethical and legal prohibitions. One way of viewing the development of a sexual relationship in the context of psychotherapy is that it is a recreation of an earlier incestuous situation for both persons. As Kluft (1989) has noted, incest victims tend to put themselves in situations where they become revictimized and therefore are "sitting ducks" for therapist-patient sex. As Freud (1905/1953) observed, "The finding of an object is in fact a refinding of it" (p. 222). Both therapist and patient are refinding forbidden objects from the past, and the therapist colludes in an enactment rather than interpreting the unconscious wish to repeat past trauma, all under the guise of "true love."

• *Misperception of wish for maternal nurturance as sexual overture.* With incest victims in particular, receiving care may be inextricably bound up with sexuality. To be reassured that they are cared for and valued, they may explicitly demand some form of physical contact. The professional boundaries of the relationship may be regarded with contempt, and the longing to be loved and held may be repeated again and again until the therapist acquiesces (Gabbard & Wilkinson, 1994). Therapists often misconstrue the patient's wish for maternal nurturance as a sexual overture and act accordingly. A pregenital need is misunderstood as a demand for genital sexual activity.

• *Interlocking enactments of rescue fantasies.* Apfel and Simon (1985) have noted that the patient's tendency to repeat his or her past may, in fact, be mirrored by the therapist's need to repeat. A female patient may have harbored a childhood fantasy that she was somehow ministering to a father who was despairing over his marriage. Similarly, a male therapist may be unconsciously rescuing his depressed mother. Hence, the therapist-patient dyad is involved in interlocking rescue enactments.

• *Patient seen as idealized version of the self.* Lovesick therapists with narcissistic problems may project aspects of themselves into the patient. This projected ego ideal or idealized self-representation may then obscure the patient's real qualities. Just as Narcissus fell in love with his own image in the water, these therapists are infatuated with an idealized reflection of themselves.

• *Confusion of therapist's needs with patient's needs.* Sullivan (1954) once noted that psychotherapy is a truly unique profession because practitioners must put aside their own needs in the interest of addressing the needs of the patient. An occupational hazard for all therapists is to inadvertently or unconsciously gratify their own needs while they think they are meeting the patient's needs. In cases of sexual misconduct, this dynamic is particularly problematic. Because many therapists grew up in homes where they felt unloved, they may attempt to elicit from their patients the love they did not receive from their parents (Gabbard, in press; Sussman, 1992). Longings to be loved are defended against by giving to others. Many lovesick therapists genuinely feel they are giving something wonderful to their patients, even though they are involved in an ethical transgression. In this manner, they defend against acknowledging their own depen-

dency longings and their use of the patient for their own gratification.

• *Fantasy that love in and of itself is curative.* This theme is also closely related to conscious or unconscious childhood fantasies that persist in adult therapists. They may feel a deep conviction that they would have been much happier as adults if they had been loved as children. Similarly, therapists who transgress sexual boundaries with patients often harbor a belief that they can love the patient better than the patient's own parents did. Many films that feature sexual relationships between therapists and patients suggest that love itself is much more curative than any technique acquired through professional training. In Barbra Streisand's 1991 film, *The Prince of Tides*, for example, the audience is left with the impression that Tom's improvement is primarily related to his love affair with his therapist, rather than to any insight or understanding related to the therapist's professional expertise.

• *Repression or disavowal of rage at patient's persistent thwarting of therapeutic efforts.* For some therapists, the patient's improvement is essential to the therapist's self-esteem. When certain patients continue to deteriorate despite the therapist's most zealous efforts, some therapists may resort to sexual relationships out of despair at the frustration of their omnipotent strivings to heal (Searles, 1979). Their rage at the patient for failing to respond is buried beneath professions of love and caring.

• *Anger at organization, institute, or training analyst.* When therapists work in institutional settings, they may develop bitterness and resentment based on their perception that the institution has mistreated them. Investigations of therapist-patient sex in such settings commonly reveal that anger has been acted out at the organization through the ethical transgression. In cases of pastoral counselors, resentment toward the church or a particular church official may be a fertile field for sexual misconduct. When an analyst is the transgressor, anger at the training analyst or institute is often involved. Such behavior may also represent an unconscious fantasy of revenge against one's parents.

• *Manic defense against mourning and grief at termination.* In every psychotherapy relationship, there is an inevitable loss. A paradox of the process is that if treatment goes well, the relationship must end. Neither the therapist nor the patient looks forward to dealing with feelings of grief and mourning at the time of termination. One defensive way to avoid such feelings is to deny the ending by beginning a new, personal relationship (Gabbard, 1990). Indeed, many cases of therapist-patient sex begin as therapy is ending.

• *The exception fantasy.* Some lovesick therapists convince themselves that their sexual relationship with a patient is somehow an exception to accepted ethical guidelines. Often these therapists will view the relationship as having transcended transference or countertransference. They may view themselves and the patient as "soulmates" who were destined to find each other and just happened to have done so in the context of a psychotherapy relationship. The love is regarded as so extraordinary that mundane ethical codes are irrelevant.

• *Insecurity regarding masculine identity.* Male therapists who engage in sex with patients are often insecure about their maleness. Some may be seeking affirmation and validation for themselves as men because they feel they did not receive that sort of affirmation from their mother or father while growing up. The sexual gratification in such cases is secondary to a validation of their gender identity.

• *Patient as transformational object.* Although it is tempting to draw parallels between the forbidden aspects of the oedipal situation in childhood and the boundary violations between therapist and patient as adults, clinical work with such therapists suggests that primitive preoedipal themes are prominent (Twemlow & Gabbard, 1989). One is the wish to be transformed by the patient. Bollas (1987) noted that the mother is initially experienced not so much as a separate person as a process of transformation: "In adult life, the quest is not to possess the object; rather the object is pursued in order to surrender to it as a medium that alters the self" (p. 14). Hence, at the most fundamental level, the therapist may harbor the fantasy that the patient will be a love object that serves as an agent of magical change.

• *Settling down the "rowdy" man.* Although most of the literature on the dynamics of therapist-patient sex has been focused on a male therapist involved with a female patient, female therapists are also prone to attempt misguided efforts to rescue male patients. In such scenarios, the patient tends to be a young man with a personality disorder diagnosis characterized by impulsivity, action orientation, and substance abuse (Gabbard, 1991a). Despite these characterological symptoms, however, the young man usually possesses considerable interpersonal charm and may have a knack for engaging females in a treatment capacity. A female clinician is often drawn to such men with an unconscious fantasy that her love and attention will somehow influence this essentially decent young man to give up his wayward tendencies and "straighten up" (Gabbard, 1991b).

In American literature and film, there is a pervasive cultural myth that a "rowdy" young man simply needs a"good woman" to settle him down. At the beginning of Clint Eastwood's 1992 film, *Unforgiven*, for example, the protagonist repeatedly comments on how he was a coldblooded murderer and a drunk until the right woman transformed him into a decent husband, father, and breadwinner. Another theme in these female therapist male patient dyads relates to

the woman's vicarious enjoyment of the danger and risk typified by her male patient's life-style.

• *Conflicts around sexual orientation.* In same-sex dyads, some therapists will use a relationship with a patient as a way of acting out conflicts around their own sexual orientation. In the Benowitz (1991) study of 15 female therapist-female patient liaisons, 20% of the therapists identified themselves to patients as heterosexual, 20% as bisexual, and only 40% as clearly lesbian. Twenty percent said they had not been sexually involved with a woman before, and 33.3% demonstrated internal conflict around their sexual orientation or sexual behavior with women. Gonsiorek (1989) has noted a similar pattern in male therapist-male patient dyads.

Masochistic Surrender

The last category involves certain therapists with fundamentally masochistic and self-destructive tendencies who allow themselves to be intimidated and controlled by a patient, even though they know the deleterious consequences of their actions. I am not using "masochistic" here in the Freudian sense of deriving pleasure from pain. Rather, I am describing a relational mode in which the therapist, usually male, allows himself to be tormented by the patient. In the typical scenario, these therapists feel badgered into increasingly escalating boundary violations as a way to prevent suicide (Eyman & Gabbard, 1991). The patient, often an incest victim, may suffer from syndromes such as posttraumatic stress disorder, dissociative disorder, or borderline personality disorder. As a result, the patient may demand some concrete domonstration of love so that the therapist extends hours, holds the patient during sessions, accepts frequent late-night telephone calls, and even gives free therapy. Therapists who fit this category attempt to accommodate these demands, even though they know better. They often feel that they have no choice. The therapist soon learns that the patient's demands are bottomless and endless and begins to feel tormented. Demands to be held escalate to demands for sexual contact that the therapist feels compelled to oblige.

These therapists characteristically have problems dealing with their own aggression. Setting limits on the patient feels as though it is sadistic. As the patient's demands escalate, the therapist uses reaction formation to defend against growing resentment and hatred toward the patient. Just at the point when the therapist's resentment is reaching monumental proportions, the patient may accuse the therapist of not caring. In such confrontations, therapists often feel that their negative feelings have been exposed. The ensuing guilt feelings lead them to accede to the patient's demands, so that aggression in either member of the dyad is kept at bay.

Clinical work with such therapists commonly reveals an over-identification of the therapist with the patient. In many cases, both parties have childhood histories of abuse. Because of this over-identification, these therapists try to gratify the patient's entitlement to be compensated for suffering as a child. Like lovesick therapists, masochistic therapists may be reenacting their own childhood abuse in addition to the patient's. Unlike lovesick therapists, however, they are not in love with the patient and often feel that they are being "dragged down" by the patient. Some therapists who have masochistically surrendered in this manner describe dissociation or depersonalization during the sexual episode. They feel as though they are just going through the motions of sex or are doing so in an altered state of consciousness.

Many of these therapists recognize the unethical nature of the sexual activity after it has happened, and they attempt to stop the therapy and seek help for themselves. In hope of receiving help, they may masochistically turn themselves in to licensing boards or ethics committees. When litigation enters the picture, they often fare far worse than therapists who are psychopatic predators because they are much less manipulative and they deal with the proceedings in a straightforward and honest manner.

Conclusion

These categories and the psychodynamic themes that accompany them should be considered tentative hypotheses that require further confirmation There may well be other sexually exploitative therapists who "fall through the cracks" and who require new categories to describe them. In addition to the heuristic value of attempting to classify such therapists, these groupings are useful in identifying which of the sexually transgressing therapists are likely to benefit from treatment and rehabilitation.

The psychopathic predators are almost always refractory to treatment because they either deny the patient's allegations or do not view them as problematic and requiring treatment. These therapists clearly should not continue in the mental health field. Although *some* persons suffering from paraphilias may be treatable in *some* settings, they, too, should not work in a field in which intense and highly intimate relationships are part of the daily practice.

Certain lovesick therapists are also unlikely to be treatable when they are in the throes of infatuation with their patient. They may be puzzled that anybody would suggest treatment for such an ecstatic mutual experience. Because they regard their love as unrelated to transference or countertransference issues, they view psychotherapy as having no purpose. When the infatuation dissipates, however, many of the lovesick therapists then have greater insight into their folly and may be amenable to psychotherapy or psychoanalysis as a way of helping them understand what

intrapsychic issues made them vulnerable to such an unethical transgression. Those therapists who have been involved in a masochistic surrender scenario generally are filled with remorse and eager to receive treatment so that they do not repeat such self-destructive behavioir.

Even with successful treatment, therapists who have acted on sexual feelings with patients should consider themselves at high risk for repeating the transgression. In most cases, they should probably avoid conducting psychotherapy and instead should confine their work to less intense forms of clinical practice.

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The Seductive Patient

*by Richard Irons, MD**

In another article in this issue of *Alabama Medicine*, Dr. Glen Gabbard has provided an overview of the problem of sexual misconduct in the medical profession. When our profession experienced a marked increase in the incidence of malpractice suits, many began to practice medicine more defensively, and documented their work more carefully. As the incidence of reports to state licensure boards of allegations of professional sexual misconduct have increased, and civil litigation has become more common, professionals have become more suspicious of the patients they serve. Our fears have been fueled by increasing publicity of peers who have become sexually or romantically involved with present or former patients. In the United States, there has been a trend toward criminalization of such unethical behavior. In fourteen states, health care professionals including physicians are subject to criminal charges if they engage in sexual misconduct. Physicians have begun to look at their patients more closely, and are more hesitant to express compassion and emotion toward their patient.



Within our practice experience, most of us are able to recall particular patients that have presented themselves for medical care who have appeared interested in more than a doctor-patient relationship. Many of us are able to identify a few occasions when our feelings toward a given patient have extended beyond professional concerns. The purpose of this paper is to explore the dynamics of attraction and seduction that may arise in these relationships.

At one time or another in practice, each of us will encounter a patient who directly or indirectly expresses interest in us that feels personal, and creates emotional responses. Some of these responses may make us feel closer to the patient. Others will induce shame, fear, confusion, and discomfort in us. We know that in the average medical practice, many patients have emotional as well as physical needs that require our attention and diagnostic acumen. The presenting complaint of a patient can be a symbolic representation or physical equivalent of emotional or intellectual needs, desires or conflicts. The body and mind cannot be easily separated.

Who are these seductive patients that we encounter in our practice? How do they consciously or unconsciously invoke emotional responses and personal reactions from us? They are not easily categorized. The very features that may attract one physician to a patient could create an aversive response in another. The vast majority of physicians are heterosexual, and may not be sensitive to or comfortable with romantic or sexual feelings from a member of the same sex directed toward us. Most of the information we have about patients who have appeared seductive to their professionals comes from studies of those who have reported professional sexual exploitation, and are the identified victims. To date, articles in the literature have primarily discussed demographics and general features of female victims of exploitive male mental health professionals. These studies have provided a profile which includes a number of common characteristics. Gutheil[1] in his survey of the literature, identified these as vulnerability, borderline dynamics, role confusion, covert hostility, and special status. Because these features also apply to

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certain patients in general medical practice, it is helpful to explore them in greater detail.

VULNERABILITY

Each person experiences some trauma in the journey from infancy to adulthood. Many emerge from even severe physical, sexual or emotional trauma unscathed, while for others, the residual effects of abuse and neglect are difficult to identify clearly even after months of therapy. They often contribute to our personality development, and profoundly affect the ways we interact with others, particularly those who are perceived to have power or control over us. Unresolved developmental trauma may be expressed in the physicians office, through a variety of physical complaints, or emotional fragility and neediness that may feel seductive in quality. Childhood physical abuse may be diagnosed in adulthood when a patient shows exaggerated somatic or emotional responses to an accident or other type of current trauma to themselves or a family member. Childhood sexual abuse may be uncovered when a patient presents for a gynecological examination, in the course of treatment of sexually transmitted disease, diagnosis of possible pregnancy or during serious illness in the offending parent or sibling. Sexually abused children commonly present in adulthood with a mixture of psychosocial problems, somatic symptoms or physical problems such as sexually transmitted diseases, eating disorders, relationship problems, or sexual disorder.[3]

The emotional incest syndrome, as described in a book by Patricia Love, is associated with parental emotional invasiveness utilized to meet adult emotional needs at the expense of a child. When a parent becomes dependent on a "chosen child" for affirmation and emotional fulfillment by placing them in the role of "surrogate spouse," this exploitation of power represents an abrogation of traditional roles and responsibilities.[2] Adult children of emotional incest often have difficulties in relationships involving a power disparity.

Some patients have been emotionally manipulated and even sexually exploited in previous relationships with teachers, counselors, clergy, or other professionals in a position of trust. The residual scars from such ethical violations often persist and affect future relationships with professionals, including physicians. The prevalence of such exploitation in our society is not precisely known. In recent years these ethical violations have been discussed more openly in the media. Reports have increased as victims have felt more support and safety in bringing allegations forward.

Pope[4] described classic symptoms often associated with therapist-patient sexual involvement that he believes result in a specific syndrome. These symptoms are listed in Table 1. Some of them may be seen when this patient comes to a physician for medical care.

THERAPIST-PATIENT SEX SYNDROME: COMMON SYMPTOMS

ambivalence in important relationships
feelings of guilt
emptiness and isolation
confusion when encountering sexual or romantic feelings
impaired ability to trust
identity, boundary and role confusion
emotional lability and cognitive dysfunction
suppressed rage
increased suicidal risk

TABLE 1- Common symptom associated with professional sexual exploitation, adapted form Pope.[4]

Many of our patients will present to the medical office while in an emotional crisis. Sometimes the patient will not reveal the nature of this crisis to the physician, or the office call will not lead into a discussion of the biopsychosocial events that may have contributed to the visit. In certain individuals, an life-changing event such as separation from their spouse or the recent death of a parent may leave them emotionally vulnerable and prone to seeking solace and comfort from someone they admire and trust: their personal physician. Other hidden problems may also contribute to a patient becoming overly dependent upon their doctor such as alcoholism, substance abuse, fear of cancer in themselves or a loved one, anxiety, depression, or some other mental disorder.

BORDERLINE DYNAMICS

As a result of past physical, emotional, or sexual abuse, a patient may develop specific highly individualized behavioral patterns that can be invoked whenever they find themselves on the bottom end of a relationship where there is a disparity in power, position, or authority. This pattern may be activated by a history of neglect or rejection rather than abuse, and is often gender specific toward the sex of the individual who previously hurt them deeply. These behavioral patterns can be referred to as borderline dynamics. They should not be equated with borderline personality disorder though there are common features. These patients often feel numbness or emptiness in their current life, and seek out affect intensifying experiences to help them feel more real, affirmed, and alive. They often harbor fantasies of being rescued by a prince or princess who will make their lives perfect and make their dreams come true. They may impulsively and unpredictably pursue objects of fantasy and desire, with potentially disastrous consequences in what is referred to as repetition compulsion. This term was coined by Freud to define the tendency of individuals

to repeat past behavior despite the suffering experienced with it, in an attempt to gain mastery over the initial trauma. For example, a woman who has been previously abused and exploited by 45 year old man many years ago when she was an adolescent, that has a history of sexual encounters with a series of men in this age range in which she has failed to achieve intimacy or meaningful relationship. The symptoms referred to in Table 1 are common in such patients. These symptoms may be combined with the behaviors described above to form a ritualized pattern that is repeated over time.

ROLE CONFUSION

Patients who appear seductive to the physician will commonly have significant confusion about proper and appropriate doctor and patient roles. They may find that a given physician reminds them of an authority figure that provided guidance and assurance, or a previous lover, and project those same positive feelings on the physician. Patients often idealize professionals, and are strongly motivated to comfort or please while harboring expectations that can never be realized within the doctor-patient relationship. In such a situation, a hug given by the professional to express comfort or support may be interpreted to signify mutuality of erotic or romantic interest. The physical contact required to complete physical examination or a diagnostic procedure may feel erotic rather than diagnostic to the patient, bringing confusion to the interaction. The busy practitioner leaving the room to see another patient may not even notice a change in the patient's demeanor and level of comfort. The patient may leave the physician office unsure of whether anything unprofessional or inappropriate has occurred, yet feel uncomfortable and upset about the feelings the encounter has engendered.

COVERT HOSTILITY

Many of our patients are uncomfortable with the patient role. There is a substantial disparity in power, medical knowledge and experience. Differences in age, education, social and economic status, and life experiences commonly separate doctor and patient. It is difficult for one to feel equal and a genuine partner in the management of health concerns. Despite this education and training, physicians cannot heal all medical problems. In some cases, a patient may actually deteriorate due to a undiagnosed and untreated medical problem or an untoward side effect of a medication. There are also chronic medical problems that do not seem to improve no matter what the physician and patient try. In such situations, the patient's idealized image of the doctor may tarnish, and the professional may be the recipient of a different kind of patient transference – unresolved anger toward an authority figure. The patient may come to envy the professional, or resent the fact that the doctor has failed to resolve the medical problems. The patient may hold the doctor responsible for the medical expenses incurred, especially when lab tests, expensive procedures, days of missed work, and costly medicines have failed to alter the progression or chronicity of medical problems. The patient may feel more dependent on the physician, while at the same time angry and frustrated, holding the doctor responsible for the failure to return to health. The use of seduction to achieve a special relationship with the doctor is one way for the patient to gain power in the relationship. The patient may desire the attainment of special status and attendant power over the doctor, but may simultaneously wish to be dominated and ruled by the physician, perhaps in the manner the patient has been dominated by other authority figures or a spouse in the past. Patients are also prone to transfer or "displace" anger toward another person in their personal life, such as an abusive spouse, upon their doctor who is less threatening.[7]

SPECIAL STATUS

Everyone likes to feel special. When a patient has privileged access, then the patient's expectation of the doctor usually becomes permanently altered. The patient may get special treatment through fee discounts, quantities of medicine samples, or extra time for their appointment. The patient may be the recipient of home visits, obtain care at the office after hours rather than in the emergency room, or be seen when the doctor is not on call. Gifts may be exchanged. Frequent telephone calls maintain close contact. Through such actions patient becomes confidant that the doctor does view them as unique, and feels their special status has been affirmed. The fosters greater idealization and projection in the relationship, and may in retrospect be interpreted by either or both parties as seduction. It may well foster rumors and suspicions in medical peers, clinic employees, or the patient's family.

THE OVERLOOKED FACTOR: PHYSICIAN VULNERABILITY

It is much easier for us to look at the weaknesses and vulnerabilities of our patients than our own. Based upon my experience in the completion of over 220 formal assessments involving allegations of professional sexual exploitation, I believe that in most instances the degree of vulnerability we carry from our own wounds will determine whether the presence of seduction in the doctor-patient relationship will lead to professional sexual misconduct or sexual offense. Let us consider woundedness from a male perspective.

In each individual, a personal, specific vulnerability develops during separation and individuation, particularly from our parents. This vulnerability may be associated with a time we were disciplined or traumatized

as a child. It may come in adolescence or early adulthood from a lost romantic love or a painful rejection. Disruptions or failures in the full integration of these significant life events results in a psychological wound, unique to the individual. Once formed. this wound has an autonomous existence which may be repressed for a period of time, but will be eventually expressed later as personal insensitivity toward another, as ambivalence in complex, emotionally demanding relationships, or in certain rigid belief systems.[5] These wounds have a profound effect upon relationships, intimacy, and erotic imagination. They become a central feature in one's mental architecture. They are an inner source of unresolved tension that exert a formative and continuing influence on our desires and perceived needs. The wounds impart upon these needs characteristic biases or patterns that are evidenced by loose knit groups of telltale signs that I am define as ritualized behavior. These behavioral patterns tend to reassert themselves over time, although their influence can be temporarily overridden through determination and willpower. These wounds are strange gifts in life which teach us about relationship and have protean forms of expression that are both creative and destructive.[6] Our wounds are not only the origin of much of our shame and guilt, but also the origin of our power. As Thornton Wilder said:

Without your wounds where would your power be? The very angels themselves cannot persuade the wretched and blundering children on earth as can one human being broken in the wheels of living. In love's service, only the wounded soldiers can serve.

SEDUCTION AS INTERACTIVE PROCESS

Either party can bring eroticized or romanticized thoughts, feelings, or gestures into the doctor-patient relationship. However for seduction to proceed to sexual or romantic involvement, an interactive process must occur involving both parties either consciously or subconsciously in most cases. Seductiveness, like fantasy or desire, is neither good nor bad. It is part of the human condition. When we are unaware that seduction is operative in our relationship with another, our words and actions are particularly susceptible to misinterpretation. On the other hand, when we can identify such instances, and address them honestly and directly, then both the patient and physician may experience what Peter Rutter describes as a healing moment:

When a forbidden-zone relationship becomes erotically charged, several moments of decision inevitably occur that determine whether the sexuality will be contained psychologically or acted upon physically. Whenever a man relinquishes his sexual agenda toward his protegee in order to preserve her right to a nonsexual relationship, a healing moment occurs.

...When a man in power relinquishes his protegee as a potential sexual partner, he also creates a healing moment for himself. In giving her up sexually, he releases both of them from the secret demand that women heal him, an underlying psychological reality that permeates so many relationships in which sexual exploitation of the forbidden zone occurs.[8]

DEVELOPING SAFE AND HEALTHY BOUNDARIES IN MEDICAL PRACTICE

Most of us have not received formal training on establishing appropriate boundaries in the medical workplace. During the past two decades, we have witnessed significant changes in acceptable boundaries and community standards for the use of chaperons during physical examinations. No professional can tell you what boundaries are required and meet current practice standards in every situation within your specific practice. Few of us have given this topic adequate reflection, however. In these days of risk management and changing medical practice standards, I encourage you to review the policies and procedures in your office and hospital. Please consider the following guidelines, which have been taught to me by the professionals who have come to our assessment program for evaluation of allegations of professional sexual misconduct or offense:

1. Post in a prominent location in your office a code of ethics to which you ascribe, such as that of the American Medical Association.
2. As a physician it is your responsibility to set the interpersonal tone and standards for appropriate humor and comments in the medical workplace. Within your own office be observant of personal and employee dress, sexual comments and innuendoes, and comments or jokes about patients.
3. In initial appointments with new patients to your practice, take the additional time to explain examination techniques before you perform them, especially when they are not likely to be known to the patient, or involve contact with areas of the body considered sexual.
4. Be cautious when revealing personal information about yourself. Consider carefully your motives for self-disclosure.
5. Beware of the patient who provides unsolicited information to you about personal relationships or sexual interests, or the patient who "dresses up" for their appointment.
6. Encourage staff members to inform you whenever they feel that a patient is either particularly upset or enamored with you. When a patient leaves your office following a procedure or physical examination, have someone in the office check to make sure they were comfortable with the interaction.

7. Be sensitive to, and trust your own feelings when interacting with a patient. If a patient feels needy and vulnerable, or evokes strong positive or negative feelings, note them and whenever possible share them with others in the medical workplace.
8. If you are interacting with a patient in history taking on physical examination and you think that it would be helpful to have a chaperon present, stop what you are doing and get one.
9. If a patient makes direct or indirect romantic or sexual overtures, note them in the medical record. Consider how you should treat the patient in the future. Occasionally, it may be necessary to ask a patient to find another care provider,
10. Review your patients. consider those that have special status. Determine if that status is safe and appropriate for your medical practice.
11. Consider carefully your motives for granting special favors. Continue to exhibit compassion in your medical practice, and allow your patients to express their feelings. Hug or touch patients when appropriate, based on the setting, the quality and length of the doctor-patient relationship, and the presence of others at the time. Remember that our touch in itself is often therapeutic.
12. Be particularly sensitive to the signs and symptoms of physical, emotional, and sexual abuse in your patient population. These patients need you to identify their past or present trauma, and provide medical care with particular attention to their need for safety in the doctor-patient relationship.

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The Implications of Sexual Misconduct In A Physician's Practice

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The AMA's Council on Ethical and Judicial Affairs has concluded that: (I) sexual contact or a romantic relationship concurrent with the physician-patient relationship is unethical; (2) sexual contact or a romantic relationship with a former patient may be unethical under certain circumstances; (3) education in the ethical issues involved in sexual misconduct should be included throughout all levels of medical training; and (4) in the case of sexual misconduct, reporting offending colleagues is especially important.[1] Alabama law § 34-24-360 provides grounds for disciplinary action by the Medical Licensure Commission based on substantial evidence of any sexual misconduct for the following offenses: (1) immoral, unprofessional or dishonorable conduct...; and (2) practicing medicine or osteopathy in such a manner as to endanger the health of the patients of the practitioner. Sexual misconduct with a patient may be grounds under either or both sections. Most studies show that the psychological impact of a physician-patient sexual contact is damaging to the patient regardless of who initiates the relationship. Sexual or romantic attraction to patients may not be uncommon. However, physicians are expected to constructively manage the emotions arising from the physician-patient relationship.

The role of the Alabama Board of Medical Examiners is to protect the patient. Initially, this role suggests significant credibility be given to the patient who makes a sexual misconduct complaint referral to the board. Investigation by the board becomes a part of the permanent record of the Board of Medical Examiners. This record would be made available to hospitals, insurance companies, and other state licensing boards when the physician signs a release.

Disciplinary actions based on allegations of sexual misconduct, after formal charges and a hearing before the Medical Licensure Commission, become public record. Members of the board are practicing Alabama physicians who are experienced with investigation of reports of sexual misconduct, including the benefits of independent professional assessment of the physician in question and the benefits some offenders may obtain from rehabilitation for their individual problem. Though protection of the patient is of primary concern to the board, evaluation, rehabilitation and return of the physician to active practice is strongly supported if patient safety can be assured.

The board receives reports alleging sexual misconduct from a variety of sources. All reports are carefully considered. Accusations without credibility are not acted upon. In some situations, a call or visit to the physician in question may resolve this sensitive issue. Complaints suggesting inappropriate sexual behaviors which exhibit reasonable grounds to be believed always result in investigation of that evidence. According to Alabama law § 34-24-361(c), if, in the opinion of the board, it appears that such information provided to it under the provision of this section may be true, the board may request a formal interview with the physician or osteopath. A few simple changes in practice will safeguard a physician from false allegations.

The most important of these safeguards is to have one of your employees present when you examine the patient, especially those of the opposite sex. This safeguard is equally significant when examining patients during hospital rounds. Some physicians include a third person in all examinations regardless of the fact that no disrobing or extensive physical contact will be undertaken. The presence of a third person not infrequently makes the patient more comfortable during examination and may further prevent any misconceptions about sexual advances during an examination. If you are alone in the examining room and talking with the patient, leave the door ajar. If you begin to perform an ophthalomoscopic retinal examination, examine the pharynx, or auscultate the chest, make sure that a third person is in the room to assist writing in the chart, to hand you things, etc., so that the "witness" aspect to their presence is not so obvious. Even non-sexual contact with a patient should be approached with caution. It may be difficult to identify strict boundaries between non-sexual and sexual touching notwithstanding that non-sexual touching may be therapeutic or comforting to patients. A third person's presence in the room will clearly define this boundary.

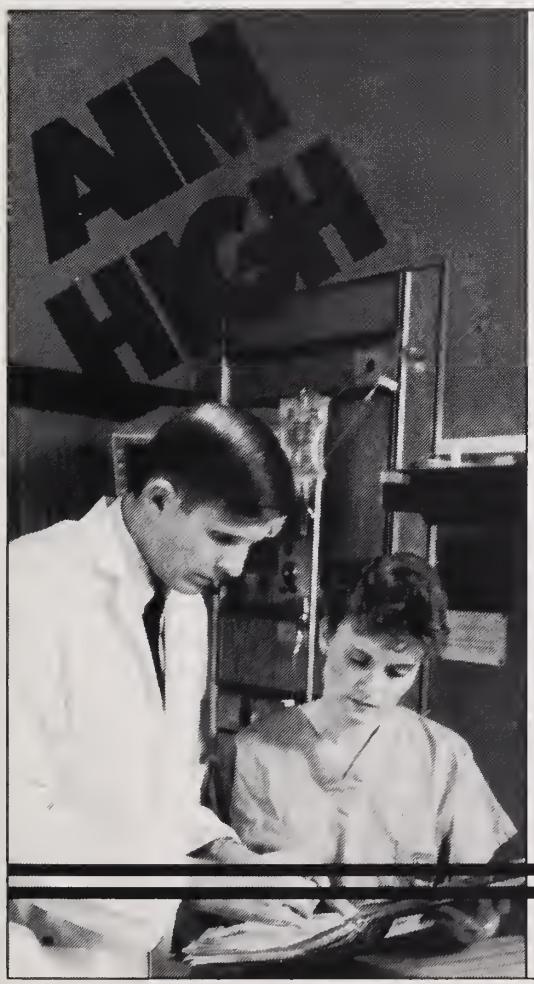
If you think you may become involved with a patient, you must immediately discontinue the

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patient-physician relationship. The patient who is unrelentingly seductive requires special caution including the presence of a third person during any interaction. Should you become uneasy with the patient's behavior, consider referral. Document the referral in the medical records. Remember, even if the patient's actions at the time indicate consenting activity, continuing to treat a patient with whom you are becoming romantically involved is to leave yourself open for later complaints against your license and possible civil suit.

A physician who engages in sexual contact with a patient seriously compromises the patient's welfare. The AMA Council on Ethical and Judicial Affairs believes that physicians who learn of sexual misconduct by a colleague must report the conduct to the local medical society or the state licensing board. Alabama law § 34-24-361(b) provides for any physician that who in good faith makes such a report to the board or to the commission shall not be liable to any person for any statement or opinion made in the report. Furthermore, Alabama law § 34-24-405 states that a report to the Alabama Impaired Physicians Committee (Physicians Recovery Network) shall be deemed to be a report to the Board of Medical Examiners for the purposes of mandated reporting of physician impairment. In this way, physicians who are accused of sexual misconduct may be able to get confidential help. Many physicians who commit sexual misconduct may benefit from rehabilitation for their problem.

Physicians need to become aware and avoid situations that have even the potential for being misconstrued as sexual misconduct. A single patient complaint, whether due to misperception or vindictiveness, can destroy a practice.



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Stress
The Profession, The Family And You

Roy W. Menninger, M.D.
*The Menninger Clinic**

This presentation was given during the opening of the 1994 International Conference on Physician Health, sponsored by the AMA, the Canadian Medical Association, the Federation of State Medical Boards, and the Federation of Medical Licensing Authorities in Canada. Dr. Menninger is Chairman of the Board of Trustees at the Menninger Foundation in Topeka, Kansas. He has a long standing interest in the health of physicians and is the author of The Medical Marriage. He is eminently qualified to discuss stress in the physician's world.

Thank you, to the AMA, not only for inviting me to participate in this way, but for having had such conferences as this and for having chosen to focus particularly on mental health aspects. I think that's an enormous indication of progress which our fields are collectively making and I am delighted to be a part of it.

My focus is not exactly what you would expect. I am not here simply to talk about stress on "the" physician. Instead, I want to talk to you as the caretakers of the caretakers and I am operating on a very simple premise that the way in which we caretakers manage stress will be reflected isomorphically in how well we take care of others. There is, I think, a domino effect, or a domino relationship, between the attitudes that we hold about our lives, about our worlds, about our relationships, about ourselves that are directly translated into the actions we take with others and it doesn't do, therefore, to simply talk about them as the ones needing care when in fact we may be in much of need, but less able to say so or less obviously in need.

Now stress is an old friend, or at least a familiar one. To most of us I think that we live in a paradoxical environment in which we are very much aware of what stress will do to others — the psychological affects, the psychosomatic affects, physical affects — but we sustain ourselves with this myth of invulnerability that that is generally what happens to others and fortunately we are reasonably well protected. Now this is characteristic of medical colleagues in general and therefore I presume it fits us as well as them. Actually, I think most of us do a reasonably poor job of managing stress. We don't recognize the results of it in ourselves, we don't even clearly understand the sources of the stress that we are experiencing. I'm not sure we acknowledge our own role in having contributed to the messes we are in. I don't think that we acknowledge the destructive impact that stress will have and I am very clear that we don't know how to manage it, nor do we know what to do about it preventively. And this is, in fact, the focus of my comments today.

As I have suggested, to care about others, I think, means that we first care about and respect ourselves. And that's quite a challenge for many of whom the self is really not their own best friend. Or as Pogo so well put it, "We have met the enemy and they is us." Now recognizing the symptoms of stress is not a difficult task. Most of us know them. The emotional evidences of anxiety or hostility or scapegoating or depression or family tensions and the physical symptoms are psychosomatic, or operating in one particular organ system or another, or the behavior changes and sleep disturbances, or withdrawal. But let me mention two aspects of symptoms of stress that you may not have thought of. One of them is that it is more obvious to others than it is to us. Now that's partly because we intentionally overlook or minimize our own symptoms. We're very good at projecting or displacing it, or more colloquially, we simply export it on to others. It's the dog that gets sick or somebody else who has the pain, but we're just fine — thank you very much. Or as somebody well put it, "Denial is not just a river in Egypt." It's alive and well and living in most physicians. Now a second aspect about stress is that as it increases the individual tends to become more like him or herself; to the point to which we may even

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become a caricature of our earlier selves. We work harder, we play harder, we laugh louder, we drink more, we make love less often. It simply means that an individual under stress calls upon the standard defensive strategies that have served well to that point, but as they become more intense, and more heavily used, they extract the essence of the self and pretty soon we become, as I say, a caricature. If we are normally rather quiet people, we become very quiet indeed. If we are normally, reasonably, independent, we may become alone or even aloof. These symptoms, I think, are not unfamiliar particularly to those of you who have seen the more extreme forms as they have manifest themselves in addictive disorders of various kinds. One might appropriately suggest that these are a kind of final pathway for many of the symptoms of stress. That they have multiple origins but perhaps rather similar outcomes in many people.

A word about the major sources of stress. There are, I'd like to say, three. Only one of which will I discuss in any detail. The first are the social expectations. This is a huge source of stress for many physicians. There are great expectations for most physicians who are now ambivalently regarded. At one time over-idealized and momentarily thereafter caustically criticized. Now, lest you think that this is a new notion, let me quote to you something that was written in 1620: "God and the doctor, we alike adore; but only when in danger, not before. The dangers are both alike requited, God is forgotten and the doctor slighted." Now there is a curious paradox: that as scientific medicine has made steady advances and our technical capabilities have exploded, making more and more diseases and disorders now treatable or at least successfully palliated, we find that the image of the physician and the social regard for the physician has been dropping steadily. How is it that we can do more and more and yet receive somehow less and less credit? It may be indeed that the contrast will be the physician at the turn of the century who had only three specific medications to offer for any disease he ever saw and yet his image, the public perception of him as a rock of Gibraltar, is now sadly eroded almost beyond recognition. Now this says nothing about the extent to which managed care may be continuing to erode the intimacy of the doctor/patient relationship or increase the distance between us and our patients, or still further alter the degree of control that we have over the therapeutic environment.

A lot could be said about that but let me go on to the second — the practice of medicine itself. Now this is for many of us, and I think particularly true for men, though to a substantial extent for many women as well, the practice itself is a source of an identity. This is me — that which I do. In Western culture, work tends to be the basis of an identity and this is particularly true when the identity you thereby achieve has so much prestige and status, to say nothing of economic sufficiency that being a physician also brings. But the practice of medicine also entails or confronts us with a very interesting strain of a role. And this is the dichotomy between the need we feel to control, a kind of disguised omnipotence, and a simultaneous sense of helplessness. These two feelings go along together and are always available to us except that we cannot always control when it is that we experience them. But there is a gap between expectations and probable performance. That is, there is a gap between life and death. Now any one of us is seldom more than partially successful. Practicing medicine is a little like Sisyphus, endlessly rolling back the stone up the hill. There is the chronic and inescapable burden of responsibility which tends to produce a kind of "over commitment" in most of us. There is, I think, an explosive growth of knowledge beyond mastery by any single person. It's estimated some 200,000 articles are published each year. Well, as a result, we are always behind. The extreme time demands are presumed to be a source of enormous stress in the practice of medicine. But, and this in fact, it is true that patients and practice will take all the time we have to give it and presumably still come back and ask for more. But conventional wisdom suggests that the shortage of time is the essential problem. In our experience in working with physicians and physician-couples suggests that this conventional wisdom is wrong. That the shortage of time is very often an excuse and that the more fundamental problem, the more fundamental reason a physician may be having difficulty in dealing with stress, has to do with some of the psychological attitudes about being a physician and in particular difficulties in managing intimacy. But in any event, whether it is the social sources or the practice of medicine itself, the notable result is that most of us physicians fail to meet our own needs, or in fact we don't even adequately acknowledge them.

Now this is partly the result of the third factor that I want to talk about; namely, the psychology of being a doctor. Now typical physicians are persons who have had very often in their early childhood experience a perception – emphasis *a perception* – of not having been adequately nurtured. A feeling that they wanted to be more taken care of than proved to be possible or at least proved to be true. And at the same time grow up in families that have an implicitly high level of expectation for performance. The result of this feeling, insufficiently nurtured, is a hunger for more, but at the same time driven to perform. There comes to be a kind of internal dialogue that goes like this: "Well let's see, if I really work hard and I really do well maybe then I'll be loved the way I'd like to be." And one sees there the beginnings of the workaholic attitudes that prevail among so many physicians. But one also sees a gradual transmutation of this wish to receive more care and nurture and it becomes pretty soon to a point

where "No, it's not I that needs the help, it's you that needs it and I'm going to take care of you." And one can see what a marvelously socially beneficial transformation this is that physicians translate their own need for care into a need to take care of others and this becomes a hallmark of the good physician indeed but it's also the first indication that the physician's need for nurture will necessarily be sidetracked or always second, third, or last in line when it comes to meeting those needs. The consequence of many children who are raised in this atmosphere, particularly with high levels of expectation, as I say, become early workaholics, but they also are on a track to becoming what we would describe the typical physician ultimately is, namely, and this is especially true for males: moderately well compensated, obsessive, compulsive neurotics, with a dominate super ego that is, conscientious ridden and depression prone. In fact, many of us would probably meet the DSM4 criteria if anybody were brave enough to take them out to take a look. The paradox of this is also important to note and that is it's the very qualities that creates this obsessive-compulsive character that also make us good physicians. It contributes to our attention to detail, it makes us hyper-conscientious and go the extra mile, a deep commitment to that person we're caring for, our patient, and a capacity to absorb and contain anger in all kinds of other negative feelings. Marvelously effective for a physician — disastrous for the person's social, personal and marital life.

Now, medical school and training unquestionably intensifies this because it makes it clear that success there depends upon knowing everything, doing everything, and doing it all perfectly. One of the things that we are taught in medical school is the concept of being successful — that we will be successful if we do all of these things. What we are not taught, however, is the definition of success. Now, by implication, it is clear in retrospect that the definition is the prevention of death. That's an interesting measure of success because at last count the incidence of death was approximately one and one and the idea that medicine will prevent death is an illusion that most of us sustain. In fact, most we can ever do is delay it, or palliate it. But we nonetheless each of us often reacts quite individually and personally to the death of a patient because we experience it as a failure of ours for having prevented that which we are presumably trained to do. But as a psychology of a physician evolves and we become increasingly compulsive, we develop a kind of perfectionistic, impatient and demanding attitude that is unfortunately hard enough for others to live with but it very often means that we are chronically dissatisfied ourselves. Nothing we ever do is quite good enough, or put otherwise, we could always have done it a little better if we had just thought of this or read that article or talked to this consultant.

We are workaholics, as I have suggested, partly for reasons to do with our early perception of experiences and what followed, but overworked serves some very important functions and they should not be minimized. In the first place, it's a justifiable way of having to be intimate with one's family and second, overwork is an expiation of guilt for not having been intimate with one's family. Overwork is an excellent means of absorbing anger. And lastly, it is fundamentally our way of trying to earn the love that we feel that we want, are afraid that we will never get, and maybe secretly fearful we do not even deserve.

The consequence of being a compulsive physician of this sort is that most of us are markedly guilt prone. Most physicians repeat what I call the "not enough" litany. It goes like this: "I am not taking good enough care of my patients; I haven't done enough, well enough, soon enough; I haven't read enough. I don't spend enough time with my children. I don't do enough with my wife." And last and very much least or maybe not at all: "I don't take good enough care of myself" Physicians who are compulsive personalities tend to have an exaggerated sense of responsibility. It is linked to these guilt feelings because it leaves many of us to think that anything that happens is somehow our fault. As I have suggested, if a patient dies, it is because of something that we failed to do. Part of this exaggerated sense of responsibility is the fact that it is very difficult for most of us to ask for help. I don't know what is the incidence of physicians who refuse to ask directions when they are lost might be, but I doubt that it is any higher than the general population. But I am sure that it's no lower.

One of the things that being an obsessive/compulsive has brought many of us to do is a special kind of a special style of handling aggression. In effect, we become passive/aggressive. We let other people be angry, partly as a result of our manipulating the situation so that we don't have to confront the anger, we don't have to be angry and we don't have to manifest the hostility. It is somehow that many physicians are so concerned about manifesting overt aggression that it suggests that many find that being liked may be more important than being right and certainly more important than winning. And so many physicians have developed a strategy for avoiding conflict. Averse even to strong statements or strong opinions for fear this will antagonize the listener. An assertive behavior, even when it is justified, sometimes smacks in the mind of this kind of physician as evidence of being aggressive or hostile. The risk for the physician is that the limited love which we receive may be even less if we are angry at the people around us.

Well, the conclusion one has to draw is that many physicians don't get much fun out of life. As one put it, this physician was about to go off on vacation and described to me what he has to do first: "First, I get all

of my paper work up-to-date, even though it means staying up for five successive nights until two. Then I've got to be sure all of my loose notes and papers on my desk have been filed or disposed of and I've left directions for my office staff and referral memos to the colleagues who will be covering for me that will anticipate every single possibility or contingency that might arise while I'm gone. Then, I set aside all the articles and books I've got to get read while I'm gone, pack them in a large suitcase to take with me so I know that every moment of my vacation time is well and fully used." Well, fortunately none of us is quite like that! One could properly ask the question, true that this may apply to male physicians, does it apply equally well to females? I think the answer to that is "yes and no." The yes answer comes to the extent that women physicians are caught up in the same psychological immeshment, not only of an earlier childhood but through medical school and are also compulsive, then the answer is unequivocally yes. They have not only the same pressures to perform and to do well as the male physicians, but they have also the same liabilities in trying to do so. But as a general rule, the problems of women physicians have been submerged to the sight of most of us. Problems in the academic setting of managing a home and husband, as well as, practice that many female physicians who are caught up in these problems have some noteworthy gender and role specific differences. They are more likely than male physicians to feel that work impinges on other responsibilities; like, home, family and child rearing. They consistently report more difficulty than male physicians in being listened to, or heard, or understood, or believed in a generally male environment. They are commonly expected to fit into role stereotypes, but criticized and demeaned when they do. If they act too feminine, then they are simply using their sex to make the point, or if they are too assertive they are just being "bitchy" and it is as if the scope of reaction, or a scope of action for many women physicians, is markedly restrictive. Division of labor in a medical marriage ostensively means that the men carry a significant part of the household responsibilities. Very commonly the men are very proud when they have washed the dishes and want to make sure that others know about it. The credit for that hardly being equivalent when it is the wife that does the work. One study suggested that 80 percent of female physicians still do their own housework and cooking. Although 70 percent of the female physicians with male physician husbands have significantly more responsibility for child rearing and domestic tasks. Even when they have a physician for a husband. The result is that most women physicians try to be super-women. They try to do it all. They try to be the adequate mother, the adequate homemaker, and the adequate practitioner. And the result is very often an enormous strain which goes unrecognized by a great many of the rest of us. Dual career marriage couples, dual medical marriages, are slowly increasing. Now about 60 percent of female academic M.D.s are married to other physicians and most female M.D.s who don't marry physicians will marry some other professional. What this suggests is that the numbers will increase, particularly as the number of women in medicine steadily increases, but there are special problems for dual career marriages. Such marriages do not have as much reserve capacity in case something goes wrong, such as a sick child or a broken home appliance or failed transportation. It's much more difficult for two family members than for one to live close to the edge of the impossible, day after day.



Well, the long range consequences of what I've described, I think are apparent. For many physicians a sense of feeling guilty that any attention to ones own needs takes away from things that he should be doing. It reinforces the denial of those needs and means that they often go yet unmet further. And there are progressive limitations in affect. Physicians as they grow older seem to be less capable of any emotional expression at all, as if their worlds have flattened out into a gray zone, a kind of monochromatic affect. What this really portrays is a kind of chronic depressed state which will be often characterized with a progressive withdrawal from relationships except those which are most important or most immediate. And here I refer unfortunately to the practice, not to the marital relationship. This is often intensified by the normal issues of middle years, a heightened sense of directionalness, a heightened sense of doubt about choices made, wonderings, regrets, and so worth. And of course, at ultimately a greater risk for substance abuse, stress related illness, depression, suicide and patient and practice neglect.

Let me assume you nonetheless are able to respond

to the points I wish to make about what attention you give to your own needs. This is a difficult challenge, I realize. Most of us don't think comfortably about the self We are taught not to. That's a sign of selfishness. We're not encouraged, we may even be forbidden. But the truth of the matter is, as I have suggested, that failing to have some thought about these needs means that they won't get met at all. But doing this takes an acknowledgement of a certain kind of personal responsibility. I put these in terms of questions to be asked. The thing about these questions is not that I have the answer. They are questions which you ought to formulate to yourself and to consider for yourselves what those answers point to. Consider them work questions.

The first is goals and objectives — whether you have any at all. No, most of us are too busy, "I'm sorry, come back tomorrow." The pressures of daily routines for must of us mean that life is a mindless extension of the past into the future. Planning be damned. There isn't time for that. Of course, no time for planning means there's no time for reflection either, but it also means that such goals as we have are commonly set by somebody else. And most obviously, of course, it's the practice or the patients, sometimes the family or the family's needs, but in any case — it ain't us. Those of us who do have goals, and we do have a few, we could characterize them in very specific and rather concrete ways. We tend to use two verbs out of a potential three to talk about them. Those verbs are "having" or synonymously owning, possessing, or buying; and "doing" or its synonyms of achieving, or creating, or building. Now the advantage of those verbs, of course, is that whatever they produce is highly visible. We can see it and so can others. What's more, what we do so concretely lends itself to being counted and we can actually see if we have now more of that than we had last year. If we now have three cars, two houses and one boat — that's better than only two cars, one house...but think what it would be if you had four cars, three houses, two boats, and an airplane, or six houses...well, I'm already lost, but that's the point. Anything you have that is measurable as a definition of your goal is vulnerable to interesting criticism. Any number you can think of, I can think of one larger and I can ask you why that isn't better? One of my colleagues, a psychiatrist who's publishing a good many papers, told me that his plan is to publish five papers this year. I said, well that's great, but why five? He said, "I only published four last year." Well, I could see his point. Five being larger than four was clearly better. What I knew, I'm not sure that he knew that I knew it, and I don't think that he knew that he knew it, or that he didn't know it — is that the five papers that he published this year were only rehashes of one he published ten years ago! That didn't matter. He was still able to make this curious transmutation of quantity equals quality. As if there were no distinguishable difference. That bigger is better and that more is better.

Well, let me read you a short parable that caricatures this concept that quantity is a measure of all good things. It is the parable of the snake. In the beginning, God didn't just make one or two people. He made a bunch of us. Because He wanted us to have a lot of fun and He said, "You can't really have fun unless there is a whole gang of you." So He put us in this playground park place called Eden and told us to enjoy. At first, we had fun just like He had expected. We played all the time. We rolled down the hills, we waded in the streams, we climbed the trees and swung in the vines, we ran in the meadows, frolicked in the woods. We hid in the forests and just acted silly. We laughed a lot. Well, then one day this snake told us that we weren't really having fun because we weren't keeping score. Well, back then we didn't know what 'score' was. When he explained it we still couldn't see the fun. But he said that we should give an apple to the person who was best at playing, but we'd never know who that was if we didn't keep score. We could all see the point of that because each of us was sure that he was the best. Things were different after that. We yelled a lot. We had to make up new scoring rules for most of the games we played and some of them, like frolicking, we stopped playing altogether – just too hard to score. By the time God found out about our new fun, we were spending about 45 minutes in actual playing and the rest of the time working out the score. Well, God was wrought about that, very, very wrought and He said we couldn't use His garden any more because we weren't having any fun. We said we were having lots of fun and we were. He shouldn't have gotten upset because it wasn't exactly the kind of fun He had in mind. But He wouldn't listen. He kicked us out and He said that we couldn't come back until we stopped keeping score. To rub it in, or to get our attention, He told us that we were all going to die any way and that our scores wouldn't mean anything. Well, He was wrong. My cumulative, all game score, is now 16,548 and 1/2. That means a lot to me. If I can raise it to 20,000 before I die, I'll know I have accomplished something. But even if I can't, my life has a great deal of meaning now because I've taught my children to score high and they will all be able to reach 20,000 or even 30,000. Really, it was life in Eden that didn't mean very much. Fun is great in its place but without scoring — there's no reason for it. God has a very superficial view of life and I'm glad my children are being raised away from His influence. We were lucky to get out and we're all very grateful to the snake. Well, present company excluded, of course. A caricature? Perhaps. But it underscores the tyranny of numbers.

I suggested that there were two of three verbs one could use. The third verb is not so obvious as the "hav-

ing" or the "doing" verb, it is the verb "to be." But it enables one to raise the question, what kind of a person are you trying to become? What is the direction to which the quality of your life is trending you? You might think of it as what your grandson might say if asked. Booksbound put it in one way. He said,

You can use most any measure when you are speaking of success.

You can measure it in fancy home, expensive car or dress.

But the measure of your real success is one that you cannot spend.

It's the way your son describes you when he is talking to a friend.

There are some of us who would rather not be overhearing that conversation.

One way to determine what this use of the verb "to be" or "to become" might mean for you is to try composing your own epitaph, and if it is good enough, who knows it may be used when you need it. Another way to think about it, is to try writing a personal advertisement for the *New York Review of Books*. Let me read you one, "Comely, catechistic widow. That I am well informed and well schooled may be of less consequence than that I am well rounded and well educated, kind, energetic, open to life's joys. That you are over 45, is less important than that you are gentle yet masculine, have wit and wide ranging interests, perhaps even a love of Mozart and fireflies. Shall we meet to compare notes on the things that really matter?" Now, whether you would ever publish such an ad, I will leave to you, but it illustrates the interesting but difficult task of condensing into a few words what you think your own essence is that you would wish other people to be aware of and to know.

The second question after goals is to ask about your priorities. We already know what those are likely to be. You have given control of your priorities to others much as you have to your goals to your practice. Glen Gabbard and I wrote a paper on the phenomena of postponement and the way in which this insidiously becomes a kind of lifestyle. The necessity of having to postpone one's gratifications in medical school until after graduation and then discovering that you have postpone them again until you finish the early part of your graduate training and then discover that even in the latter part you have to postpone them until you are into practice and then postpone them still further until you find somebody who can cover for you on the weekends and then postpone them still further until you finally can retire and maybe then you will have time to do some of the things you have been meaning to do for so long. What it illustrates is that postponement becomes a life strategy for most of us and that we have lost the capacity to enjoy the moment for which we are living in the moment. Most of us deal with the present as if it were only a stepping stone to the future as if the future is where life really takes place and that now is a temporary inconvenience. But as you are well aware, the future does not exist; we only live in the present and yet many of us will mortgage all that we have at the moment, including the satisfactions, or the needs we have to meet, by deciding to wait until that improbable future which never arrives.

The third question that I'd want to ask is about your personal relationships. What's the quality and their significance in your life? Most of us deal with other people in quasi operational ways. That is, we deal with people because we have to or we deal with them because we need something from them, or we deal with them because we are going to do something to or for them. Very seldom do we have relationships whose very existence is the value. That it is not simply what they can do for us, or what we can do to them, that matters. This is again a reflection of this use of the verb "to be" or "to become" which is not a common part of our vocabulary. Most of us do not give much attention to the needs of others in our immediate relationships. Actually, we don't treat them as well as we might well treat the lawn mower which will show us what happens if we don't give it a kind of prophylactic care at the end of the summer — next spring, it simply won't run. Would that people had some same mechanism to say, "You do not pay the kind of attention to me that I need." But the truth of the matter is, we do not pay much attention to what we, ourselves, need in terms of our reflective interests and our reflective concerns. This tendency to deny one's needs is particularly true for the sort of self-sacrificing and masochistic individuals that most good caretakers are. To underscore the point again, being good to others extracts this curious but paradoxical cost that we are very unlikely to be as good to the self. And it is almost as if some of us think there is a real balance there if we do end up giving more to the self, does that mean that we will give less to others? Because under certain circumstances that kind of narcissism produces that kind of result. Too much investment in the self leaves to little for others.

But the sort I'm talking about really is to focus on what we are doing to recognize our own needs. Intimacy, for example. There is a confusion about what intimacy is and I, in fact, experienced that when in much younger years I was asked to give a talk on love, sex and intimacy. I said, "Well I can easily handle this, I'll just cut off the intimacy part because I think love and sex will pretty well cover the waterfront and I'll just talk about that." Well, some older person than I said, "Roy, before you do that just check out the dictionary definition of the word intimate and see what you think then." I discovered something I should have remembered from medical school — it stems from the root word meaning 'innermost', the inner-layer of the

blood vessels for example. Something that is intimate, therefore, reflects something which is innermost. Feelings, or thoughts, wishes, or fears and it is curious that in our culture the prospect of being intimate is a very scary thing for a great many men. For women it is less of a threat and it is something to wonder why there should be this difference. But for many men this somehow threatens a loss of control or maybe a damage to one's self image. I know that reflecting on ones personal fears would for many of us we would feel that this was a blow to our integrity — that we were putting ourselves down or we were showing something to others which we ourselves do not like and therefore we'd feel worse about it. It is interesting how the medical practice itself handles this issue of intimacy. Most of us are aware that physicians do have difficulty being close. Being intimate with spouses. But consider the way practice teaches us to handle intimacy. Intimacy in this case, however, means that it establishes the definition of the relationship. The patient, to be a patient, follows certain rules. There are certain acceptable definitions of how much distance, how much information, how much physical intimacy and exactly what kind. Leaving aside for the fact that there is more and more evidence of transgression, most of us understand that what medical practice does is to define a level of intimacy that, and this is the key, most physicians find adequate and sufficient. Indeed, one can even wonder if the choice of specialty we make doesn't have something to do with our attitudes about intimacy. Those who chose pathology or radiology have a different definition of closeness to the patient than, for example, surgeons, but they have a very specific definition of what kind of intimacy they will have. Or psychiatrists and the kind of intimacy which they have will be still different. And pediatricians and so on. But the problem here is that we all look for ways to handle this that are very compatible with practice and they are devastating in the setting of the home where these same rules do not apply. Part of the reason that we have difficulty with our relationships is that most of us have a very poor idea of what a mature relationship looks like. Let me suggest four characteristics that in every case should be regarded as a kind of ideal. I'm not sure that any of us has ever even seen a mature relationship — they aren't that common. The first is a sort of basic trust. A sense of a bedrock commitment with one another that in effect implies a mutual acceptance and a mutual valuing of each other. What this really means is that the next argument will not lead to a destruction of the relationship. It implies that one can share power — that one need not dominate it. The communication pattern is open and honest and often candid, but also has a degree of humor present which is directed at the issue but not at the person. It has a degree of shared giving and receiving, not simply time and space though that is in short supply in most medical marriages, but also what is innermost, as I suggested. And lastly, a relationship which is mature will be gutsy and feelingful, but the fights will be those which can be successfully resolved without destroying the relationship.

Lastly let me talk about one's personal relationship with one's self. In a way the key issue of the point that I have been stressing today. We need to be able to look at our own selves with some degree of honesty without illusion especially in terms of our expectations. Are they unrealistic? Are they too high or too rigid or too infantile? Are we too dependent on what somebody else will do first before we can define for ourselves what is important? We need to recognize our own contribution to the problem. We are very good at spotting those in others, particularly our patients. We are less likely to recognize what we have done to create the problem. As someone put it, it has taken a great many years to get us into the messes we are in and a great deal of assistance from each of us to do that. The essence, I think, is that each of us has to take a certain responsibility for our own expectations, our own feelings, our own behavior. And in order to do that, we need to develop a certain sense of self-worth and value. This self that lies within us is too often ignored until it becomes the victim of the pathology which stress is capable of inducing. And sometimes we will not discover the importance of that self and the need it has for attention, for care, for love even, except as we must first become seriously symptomatic and find ourselves in the hands of others who can help bring us back to the point of seeing that we have some worth in ourselves. But as I have suggested, in order to do good for others we must, I think, first do good for ourselves.

How would I do that? Well one would be suggest transition time. Too many of us move in polyphasic ways from one world into another with hardly a moment, except as the traffic is very slow on route home, to allow a time for transition. To alter our mindset and to prepare for reentry or to adapt to another environment and to different people. To set aside what we have been thinking and to begin to think about what will be important. An effort to try to address our need for self-esteem. Self-esteem has been defined as the disposition, to experience one's self as competent, to cope with basic challenges in life and be worthy of happiness. That is a phrase, I think, that many of us as physicians hardly understand, let alone know how to do.

Now, permission to enjoy without guilt is another characteristic of being good to the self. We need to lay off the self. We give it a hard time, we're exacting task masters for ourselves demanding perfection and high performance.

Our lives, to mention another, should reflect diversity. A life with variety, in order to achieve some depth and breath of interests, not the monochromatic pat-

tern that is true for so many physicians. We need to make further a commitment to continued growth. Growth in knowledge or in wisdom or in competence or in perspective or in skills or whatever, but a commitment of that sort entails lifetime learning. Indeed, I think that living without growth promoting learning is equivalent to death and you just haven't fallen over yet.

Lastly, make time. Nobody will give it to you so you must make the time for valued activities. Time to think and to reflect and to evaluate. Time for play to encourage the spontaneity and freedom. Now the paradox is establishing the priority of time for personal growth and development will establish a pattern for allowing time for the other important elements in your life including one's spouse and family. The point is that only you can make this judgment and only you can make the decision to do something about these needs that otherwise go unmet.

I think the ultimate responsibility that our profession knows so well is caring. We know so well how to care for others and my suggestion is that we need to give much more precise attention to care for the self. We must rescue it from thinking that to think about the self is a sign of selfishness, or a sign that one no longer cares so much about others, or that we are no longer altruistic people dedicated to the care of others. We must recognize that these are like cars and a train and that if they are not hooked to the engine of the caring for the self, that caboose of caring for others will never arrive at the station.

Let me conclude with a quote that is a favorite, one that restates what I have said in somewhat larger context, that was printed nearly forty years ago: "Nothing that is worth doing can be achieved in our lifetime, therefore, we must be saved by hope. Nothing which is true, or beautiful, or good makes complete sense in any immediate context of history, therefore, we must be saved by faith. But nothing we do, however virtuous, can be accomplished alone, therefore, we must be saved by love."

Thank you.

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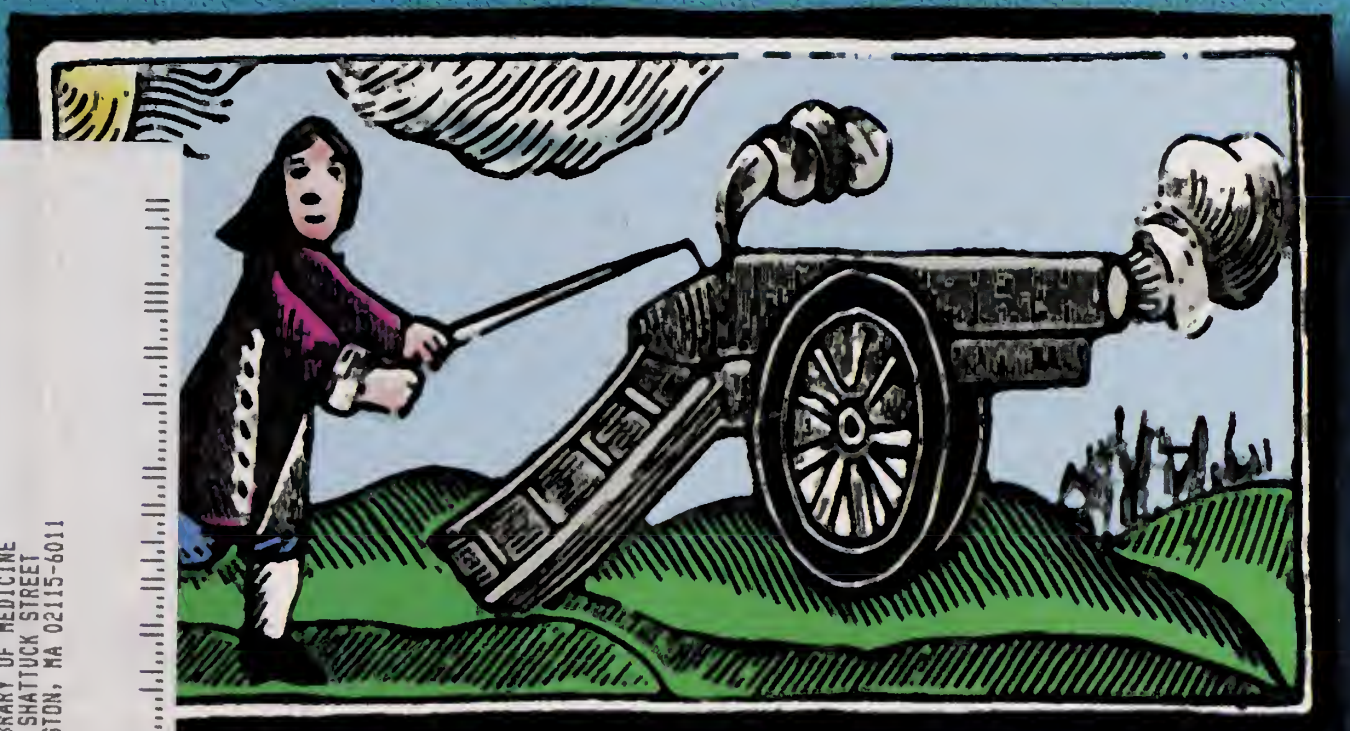
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"We dodged the Clinton bullet...



...only to face an artillery barrage..."

President Hall, page 4

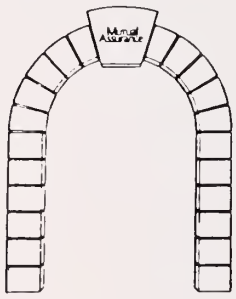
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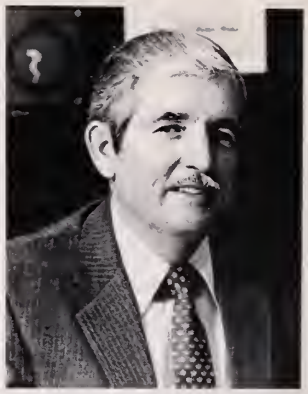
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

A Mandate for What?

Every pundit and politician from sea to shining sea has offered detailed explanations, some quite fanciful, of what the voters said in their towering rejection of Democrats last Nov. 8.

Any number can play. The Clinton White House, in deep shock, first lamely attempted to spin the catastrophe as further evidence that the American people wanted change, as they had said when they elected Mr. Clinton in 1992. Somehow, they were trying to say, the vote could not be construed as a repudiation of President Clinton but was a parallel continuation of the sentiment that defeated President Bush.

Sorry, fellows, that won't wash. Americans voted for change last November, that's for sure, but nothing in the massive Republican tidal wave could possibly be construed as affirmation of Clinton or Democrats. The awful truth the White House finally had to face was that Mr. Clinton had wrought unprecedented havoc to his party.

As is often the case in revolutions – and make no mistake about it, this was a revolution – historians will argue for generations over what precisely it meant and what it mandated. Aside from the obvious rejection of Mr. Clinton in particular and Democrats in general, I don't profess to understand the full dimensions of this epochal event, but I suspect the anger that fueled it had been building for quite some time.

The more thoughtful political analysts are in fact saying just that: Americans are in a nasty, volatile mood that places both parties and all inhabitants thereof at risk of losing their jobs.

These analysts remind us that President Bush enjoyed a lofty 90% public approval rating just after the Gulf War, but then went into a free fall that reduced his popularity by 60 percentage points in just 16 months. His high was unprecedented; but so was his fall.

Mr. Bush's rejection in '92 and Mr. Clinton's in '94 may be pieces of the same puzzle, these analysts say, adding up to a kind of free floating, non-partisan rage. Newt Gingrich, at the moment the emblematic beneficiary of that rage, has already spoken volumes on the instructions he says he received from the country Nov. 8, but others are less sure of just what the voters said.

Did they say they wanted an end to Medicare, replaced by something "more cost effective and giving them more choice," as Newt told the House Ways & Means Committee in a surprise visit the first week of the new Congress? Few others in Washington, of either party, claim to have received that message.

Some self-appointed experts argue that Mr. Clinton and his party were being punished for not bringing about health care reform. Others say they were punished for even trying, that Americans thought they had wanted a massive overhaul of the health care system, but were then repelled in horror by Ira Magaziner's involute design for federal medicine for all.

Some theorists point to the ambiguous evidence of Harris Wofford. A virtual unknown, Wofford won a surprising upset victory in a special Pennsylvania senate race in late 1991 campaigning almost entirely on the need for health care reform.

His winning campaign thus set the stage for the national debate that followed. Then, on Nov. 8, Mr. Wofford was turned down for re-election, precisely because, some analysts say, of his association with health care reform. He tried but failed. Was he rejected because he tried or because he failed?

I wouldn't touch that crazy puzzle with a ten-foot pole, my only point being that what the voters have said can be very confusing. I feel sure of only a couple of observations: Americans have come to hate and reject just about everything about Washington and

anything resembling party allegiance is fast becoming history. If nothing else is clear, it should be plain by now that the American electorate has become fiercely independent of historic loyalties to party or politicians within parties.

Reflect on this: Mr. Clinton in 1992 campaigned as an outsider who would clean house in Washington. After inauguration, it came as a shock to him and his Brownies that they were now insiders and thus suspect. Gingrich and his cohorts also ran against the entrenched establishment. Now they are insiders and thus at risk.

Long before Clinton hit the scene, I felt that the American people were really asking for something fairly simple from the central government – sharply increased benefits and sharply reduced taxes – in other words, mutually exclusive demands that can never be met by anyone, including Mr. Gingrich, short of vastly increased national debt or devastation of such as Medicare.

To promise otherwise does incalculable disservice to the nation. But few who seek voter approval dare utter that essential truth. Just for laughs, suppose I ran for national office with the following message to the voters:

"My fellow Americans, here is the reality check: we went from being the world's greatest creditor nation to the world's greatest debtor nation in a few short years.

"We're dead broke. No more freebies. Not only can you not have a tax cut, but I propose to increase your taxes to help defray some of our unpaid bills of the past generation. That free lunch wasn't free at all. Now you must pay for what you have already consumed, plus interest, before we can even consider your future Spartan diet."

How many votes do you estimate I might get for telling the people what they say they want, the truth7 They lie; they don't want that truth.

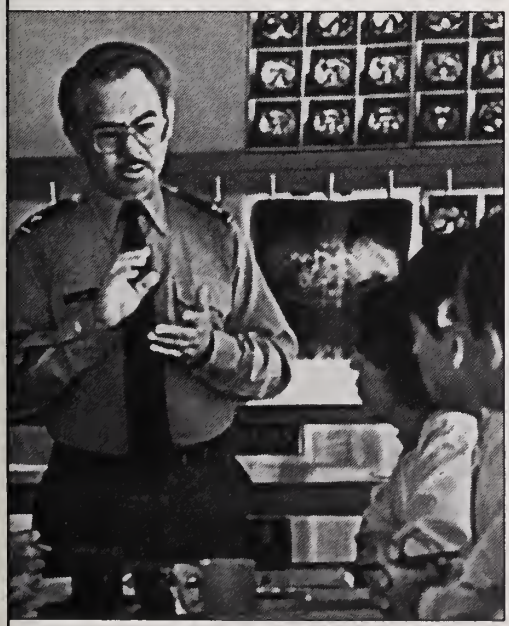
I am personally pleased, however, that they did throw the rascals out last November, if for no other reason than that I favor grand experiments of the kind that vote should usher in. But I am acutely aware of the dangers of massive social upheaval.

Every revolution, it is said, contains the seeds of the next one. Medicare is a tempting target for the Newtoids as they scrounge around to deliver on the tax-cut promise. But Medicare, for all its shortcomings, is deeply entrenched in American life.

If the Gingrich revolution tries to gut it, a Clinton veto, sustained or not, just might reelect him in much the same manner as the excesses of the Republican 80th Congress, elected in the post-war year of 1946, re elected Harry Truman in 1948, despite Mr. Truman's plummeting popularity.

If you come right down to it, Mr. Clinton's only hope of re-election would appear to be the entirely possible eventuality that the Gingrich-led assault forces will run amok.

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PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

That Lonesome Road

I suppose it would be appropriate in this, my first column for 1995, to unveil for your benefit a clear view of what the year holds for medicine.

To be honest, however, I admit to being deficient in what former President Bush lightly dismissed as the "vision thing." In any case, prophecy is the frailest of human gifts and I have never wasted much time trying to read tea leaves.

Suffice it to say that I did not predict the trajectory of 1994 and therefore can lay no claim to possessing over-the-horizon radar for this year. As last year began, I thought Congress would pass some kind of health care reform. So did most people, although the woods are now full of folks who say they knew all along that it would not come to pass.

Many physicians took temporary leave of their senses in 1994, quaking in their boots over the prospect of a radical transformation of American medicine propelled by the considerable powers of persuasion of a First Lady who burned with the hard, gemlike flame of deep personal commitment. In the months preceding the beginning of 1994 she appeared to be propelled by a mighty wave of popular sentiment that would sweep away all obstacles.

That didn't happen. Looking back, it is clear now that it never came close to happening. The reason it didn't, I am persuaded, is that Bill and Hillary were convinced they had been anointed by history to completely redesign one-seventh of the U.S. economy, heaving out the window centuries of evolved institutions and custom, much as they might have cleaned out an old barn back in the Ozarks.

Their undoing was, in my judgment, their megalomania, first seen in Hillary's secret committee, an alien concept out of which was produced another alien concept, the Ira Magaziner 1,400-page atrocity. It proved a non-starter, and the people were well ahead of their elected representatives in rendering that verdict.

Had the Clintons' reach not exceeded their grasp in such a grotesque fashion, it seems more than likely that some kind of modest health care reform would be the law of the land as 1995 began. I believe their overweening ambition to put their stamp on U.S. health care history was as much the reason behind their repudiation in November as anything else. Their proposal was perceived – rightly, I think – as recklessly radical by a nation that doesn't look kindly on radicalism.

But that is hindsight; we can all see pretty clearly in the rearview mirror. The gift of foresight is not as widely distributed among the general population.

Just as few of us could have predicted the utter collapse of health care reform, neither could many have foreseen the full rapacity of the private sector in its mad rush to fill the vacuum left by government abdication. As 1994 came to an end, managed care – in all its permutations, from the benign to the malignant – was spreading across the landscape with a speed and ferocity that few could have foreseen.

And that is the nature of the beast looming over 1995, as hard-eyed multimillionaire businessmen grab the torch dropped by the Clintons to impose their own profit-driven ideas on the delivery of health care in America. We dodged the Clinton bullet only to face an artillery barrage.

Some evidence of how much they have already removed from the health care system was the recent *Wall Street Journal* report that HMOs have stashed away so many billions in surplus cash that they are worried about what to do with it all. The favorite answer so far: buy still more hospitals, medical prac-

tices and managed care operations.

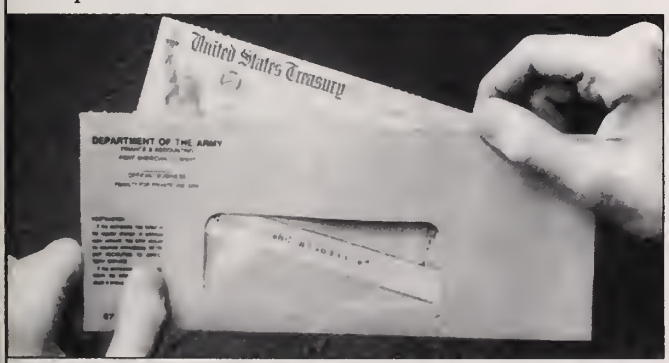
Where did all that money come from? I cannot believe their claims that the introduction of sound management principles and efficient operations could have accounted for such vast sums. Much of it had to come, one way or another, from patient care not provided.

Against this background of commercial greed, we have a new and totally unpredictable Congress, under pressure from organized medicine from one side to level the playing field for physician involvement and to preserve the sanctity of medical judgment; while from the other side health care moguls will be pouring their unlimited millions into lobbying efforts to preserve their unfettered hunting rights.

In short, it will be another turbulent year. Once again, my plan is to continue to provide the best possible patient care, come what may. I strongly recommend that course of action for you. A certain amount of fatalism may not be inappropriate. I believe the glass is still half full.

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HCFA's Evaluation and Management Services:

New Documentation Guidelines for Physicians

*by Stanley Forston, Jr., M.D., M.P.H.**

The Health Care Financing Administration (HCFA) is introducing a new physician educational program to assist physicians in the proper documentation for Evaluation and Management (E/M) services. This paper presents the guidelines for documentation as developed by the American Medical Association and HCFA. All physicians should keep in mind that appropriate documentation supports the clinical management and level of service rendered to each patient.

HCFA has previously restricted Medicare carriers in their medical review activities related to E/M codes. Since their introduction in 1992, CPT[1] codes for E/M services have not been included in the medical review process. HCFA believed physicians needed additional information about how to document services and carriers needed additional information on evaluating medical records. HCFA now plans to expand carriers' medical review responsibilities to include E/M services.

Prior to incorporation of E/M services into the review process, HCFA is providing additional physician education through the spring of 1995. Through the collaborative efforts of HCFA and the American Medical Association, the documentation guidelines set forth in this article have been developed as the basis for a comprehensive physician education program. These guidelines are intended to serve the following purposes:

(1) to provide physicians with an understanding of the information necessary to document the appropriate level of service for E/M codes, and

(2) to provide carriers with consistent guidance for medical review of physician records.

In addition to publishing these guidelines, the Carrier Medical Director's Office at Blue Cross and Blue Shield of Alabama will be involved in other educational activities designed to increase physicians' awareness of the importance of documentation for E/M services. It is anticipated that the educational efforts will continue for the next four to six months, giving adequate opportunity for all physicians to be exposed to an explanation of the guidelines. Following the educational period, there will be a three month interval during which providers' billing patterns may be reviewed and further education can be offered.

Thereafter, the Carrier will be instructed by HCFA to employ these guidelines in the review of E/M claims.

The guidelines for documentation emphasize three key components in selecting an appropriate CPT code for E/M services. The components are **history, physical examination**, and **medical decision making**. Each component has four modifiers, one of which best describes the component's contribution to the patient encounter. The three components and their modifiers may be summarized as follows:

HISTORY
- Problem Focused
- Expanded Problem Focused
- Detailed
- Comprehensive

PHYSICAL EXAMINATION
- Problem Focused
- Expanded Problem Focused
- Detailed
- Comprehensive

MEDICAL DECISION MAKING
- Straight-forward
- Low Complexity
- Moderate Complexity
- High Complexity

The guidelines offer detailed instructions for the determination of an appropriate level of E/M service using the above components and their modifiers. Each physician is encouraged to familiarize him/herself with the principles of documentation as described in this article. A better understanding of the documentation process should lead to more accurate coding for E/M services. In addition, physicians will have a refer-

*Stanley Forston, Jr., MD, MPH – Carrier Medical Director, Associate Corporate Medical Director, Blue Cross and Blue Shield of Alabama

[1] AMA copyright. All five-digit numeric procedure codes used in this booklet are from the Physicians' Current Procedure Terminology book published by the American Medical Association.

ence for the medical necessity and utilization review standards employed by HCFA and the carriers. The Carrier Medical Director's Office welcomes comment or discussion regarding these guidelines. Thoughtful input from the practicing physician community will continually improve the quality of our programs.

FROM THB HEALTH CARE FINANCING ADMINISTRATION AND THB AMERICAN MEDICAL ASSOCIATION

FORWARD

These guidelines have been jointly developed by the American Medical Association and the Health Care Financing Administration. Our mutual goal is to provide physicians and claims reviewers with advice about preparing or reviewing documentation for Evaluation and Management (E/M) services. In developing and testing the validity of these guidelines, special emphasis was placed on assuring that they:

- are consistent with the clinical descriptors and definitions contained in Physicians' Current Procedural Terminology (CPT);
- would be widely accepted by clinicians and minimize any changes in record-keeping practices; and
- would be interpreted and applied uniformly by users across the country.

The AMA and HCFA wish to thank the CPT Editorial Panel, the CPT Advisory Committees, the Practicing Physicians Advisory Council, and the Medicare Carrier Medical Directors for their thoughtful advice, comments, and direction concerning the many complex issues that were addressed in the development of these guidelines. The AMA and HCFA are committed to continually improving these guidelines and welcome comments based on their usage.

DOCUMENTATION GUIDELINES FOR EVALUATION & MANAGEMENT SERVICES

I. INTRODUCTION

WHAT IS DOCUMENTATION AND WHY IS IT IMPORTANT?

Medical record documentation is required to record pertinent facts, findings, and observations about an individual's health history including past and present illnesses, examinations, tests, treatments, and outcomes. The medical record chronologically documents the care of the patient and is an important element contributing to high quality care. The medical record facilitates:

- the ability of the physician and other health care professionals to evaluate and plan the patient's immediate treatment, and to monitor his/her health care over time.
- communication and continuity of care among physicians and other health care professionals involved in the patient's care;
- accurate and timely claims review and payment;
- appropriate utilization review and quality of care evaluations; and
- collection of data that may be useful for research and education.

An appropriately documented medical record can reduce many of the "hassles" associated with claims processing and may serve as a legal document to verify the care provided, if necessary.

WHAT DO PAYERS WANT AND WHY?

Because payers have a contractual obligation to enrollees, they may require reasonable documentation that services are consistent with the insurance coverage provided. They may request information to validate:

- the site of service;
- the medical necessity and appropriateness of the diagnostic and/or therapeutic services provided; and/or
- that services provided have been accurately reported.

II. GENERAL PRINCIPLES OF MEDICAL RECORD DOCUMENTATION

The principles of documentation listed below are applicable to all types of medical and surgical services in all settings. For Evaluation and Management services, the nature and amount of physician work and documentation varies by type of service, place of service and the patient's status. The general principles listed below may be modified to account for these variable circumstances in providing E/M services .

1. The medical record should be complete and legible.
2. The documentation of each patient encounter should include:
 - reason for the encounter and relevant history, physical examination findings and prior diagnostic test results;
 - assessment, clinical impression or diagnosis;
 - plan for care; and
 - date and legible identity of the observer.
3. If not documented, the rationale for ordering diag-

nostic and other ancillary services should be easily inferred.

4. Past and present diagnoses should be accessible to the treating and/or consulting physician.
5. Appropriate health risk factors should be identified.
6. The patient's progress, response to and changes in treatment, and revision of diagnosis should be documented.
7. The CPT and ICD-9-CM codes reported on the health insurance claim form or billing statement should be supported by the documentation in the medical record.

III. DOCUMENTATION OF E/M SERVICES

This publication provides definitions and documentation guidelines for the three key components of E/M services and for visits which consist predominately of counseling or coordination of care. The three key components—history, examination, and medical decision making—appear in the descriptors for office and other outpatient services, hospital observation services, hospital inpatient services, consultations, emergency department services, nursing facility services, domiciliary care services, and home services. While some of the text of CPT has been repeated in this publication, the reader should refer to CPT for the complete descriptors for E/M services and instructions for selecting a level of service. **Documentation guidelines are identified by the symbol •DG.**

The descriptors for the levels of E/M services recognize seven components which are used in defining the levels of E/M services. These components are:

- history;
- examination;
- medical decision making;
- counseling;
- coordination of care;
- nature of presenting problem; and
- time.

The first three of these components (i.e., history, examination and medical decision making) are the key components in selecting the level of E/M services. An exception to this rule is the case of visits which consist predominantly of counseling or coordination of care; for these services time is the key or controlling factor to qualify for a particular level of E/M service.

For certain groups of patients, the recorded information may vary slightly from that described here. Specifically, the medical records of infants, children, adolescents and pregnant women may have additional or modified information recorded in each history and examination area.

As an example, newborn records may include under history of the present illness (HPI) the details of mother's pregnancy and the infant's status at birth; social history will focus on family structure; family history will focus on congenital anomalies and hereditary disorders in the family. In addition, information on growth and development and/or nutrition will be recorded. Although not specifically defined in these documentation guidelines, these patient group variations on history and examination are appropriate.

A. DOCUMENTATION OF HISTORY

The levels of E/M services are based on four types of history (Problem Focused, Expanded Problem Focused, Detailed, and Comprehensive.) Each type of history includes some or all of the following elements:

- Chief complaint (CC);
- History of present illness (HPI);
- Review of systems (ROS); and
- Past, family and/or social history (PFSH).

The extent of history of present illness, review of systems and past, family and/or social history that is obtained and documented is dependent upon clinical judgement and the nature of the presenting problem(s).

The chart below shows the progression of the elements required for each type of history. To qualify for a given type of history, all three elements in the table must be met. (A chief complaint is indicated at all levels.)

History of Present Illness (HPI)	Review of Systems (ROS)	Past, Family, and/or Social History (PFSH)	Type of History
Brief	N/A	N/A	Problem Focused
Brief	Problem Pertinent	N/A	Expanded Problem Focused
Extended	Extended	Pertinent	Detailed
Extended	Complete	Complete	Comprehensive

- *DG: The CC, ROS and PFSH may be listed as separate elements of history, or they may be included in the description of the history of the present illness.*
- *DG: A ROS and/or a PFSH obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information. This may occur when a physician updates his or her own record or in an institutional setting or group practice where many physicians use a common record. The review and update may be documented by:*

 describing any new ROS and/or PFSH information or noting there has been no change in the information; and

 - *noting the date and location of the earlier ROS and/or PFSH.*
- *DG: The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.*
- *DG: f the physician is unable to obtain a history from the patient or other source, the record should describe the patient's condition or other circumstance which precludes obtaining a history*

Definitions and specific documentation guidelines for each of the elements of history are listed below.

CHIEF COMPLAINT (CC)

The CC is a concise statement describing the symptoms, problems, condition, diagnosis, physician recommended return, or other factor that is the reason for the encounter.

- *DG: The medical record should clearly reflect the chief complaint.*

HISTORY OF PRESENT ILLNESS (HPI)

The HPI is a chronological description of the development of the patient's present illness from the first sign and/or symptom or from the previous encounter to the present. It includes the following elements:

- location,
- quality,
- severity,
- duration,
- timing,
- context,
- modifying factors, and
- associated signs and symptoms.

Brief and ***extended*** HPIS are distinguished by the amount of detail needed to accurately characterize the clinical problem(s).

A ***brief*** HPI consists of one to three elements of the HPI.

- *DG: The medical record should describe one to three elements of the present illness (HPI).*

An ***extended*** HPI consists of four or more elements of the HPI.

- *DG: The medical record should describe four or more elements of the present illness (HPI) or associated comorbidities.*

REVIEW OF SYSTEMS (ROS)

A ROS is an inventory of body systems obtained through a series of questions seeking to identify signs and/or symptoms which the patient may be experiencing or has experienced.

For purposes of ROS, the following systems are recognized:

- Constitutional symptoms (e.g., fever, weight loss)
- Eyes
- Ears, Nose, Mouth, Throat
- Cardiovascular
- Respiratory
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Integumentary (skin and/or breast)
- Neurological
- Psychiatric
- Endocrine
- Hematologic/Lymphatic
- Allergic/Immunologic

A ***problem pertinent*** ROS inquires about the system directly related to the problem(s) identified in the HPI.

- *DG: The patient's positive responses and pertinent negatives for the system related to the problem should be documented.*

An ***extended*** ROS inquires about the system directly related to the problem(s) identified in the HPI and a limited number of additional systems.

- *DG: The patient's positive responses and pertinent negatives for two to nine systems should be documented.*

A ***complete*** ROS inquires about the system(s) directly related to the problem(s) identified in the HPI plus all additional body systems.

- DG: At least ten organ systems must be reviewed. Those systems with positive or pertinent negative responses must be individually documented. For the remaining systems, a notation indicating all other systems are negative is permissible. In the absence of such a notation, at least ten systems must be individually documented.

PAST, FAMILY AND/OR SOCIAL HISTORY (PFSH)

The PFSH consists of a review of three areas:

- past history (the patient~s past experiences with illnesses, operations, injuries and treatments);
- family history (a review of medical events in the patient's family, including diseases which may be hereditary or place the patient at risk); and
- social history (an age appropriate review of past and current activities).

For the categories of subsequent hospital care, follow-up inpatient consultations, and subsequent nursing facility care, CPT requires only an "interval" history. It is not necessary to record information about the PFSH.

A ***pertinent*** PFSH is a review of the history area(s) directly related to the problem(s) identified in the HPI.

•*DG: At least one specific item from any of the three history areas must be documented for a pertinent PFSH.*

A ***complete*** PFSH is of a review of two or all three of the PFSH history areas, depending on the category of the E/M service. A review of all three history areas is required for services that by their nature include a comprehensive assessment or reassessment of the patient. A review of two of the three history areas is sufficient for other services.

•*DG: At least one specific item from two of the three history areas must be documented for a complete PFSH for the following categories of E/M services: office or other outpatient services, established patient; emergency department; subsequent nursing facility care; domiciliary care, established patient; and home care, established patient.*

•*DG: At least one specific item from each of the three history areas must be documented for a complete PFSH for the following categories of E/M services: office or other outpatient services, new patient; hospital observation services; hospital inpatient services, initial care; consultations; comprehensive nursing facility assessments; domiciliary care, new patient; and home care, new patient.*

B. DOCUMENTATION OF EXAMINATION

The levels of E/M services are based on four types of examination that are defined as follows:

- ***Problem Focused*** — a limited examination of the affected body area or organ system.
- ***Expanded Problem Focused*** — a limited examination of the affected body area or organ system and other symptomatic or related organ system(s).
- ***Detailed*** — an extended examination of the affected body area(s) and other symptomatic or related organ system(s).
- ***Comprehensive*** — a general multi-system examination or complete examination of a single organ system.

For purposes of examination, the following body areas are recognized:

- Head, including the face
- Neck
- Chest, including breasts and axillae
- Abdomen
- Genitalia, groin, buttocks
- Back, including spine
- Each extremity

For purposes of examination, the following organ systems are recognized:

- Constitutional (e.g., vital signs, general appearance)
- Eyes
- Ears, nose, mouth and throat
- Cardiovascular
- Respiratory
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Skin
- Neurologic
- Psychiatric
- Hematologic/lymphatic/immunologic

The extent of examinations performed and documented is dependent upon clinical judgement and the nature of the presenting problem(s). They range from limited examinations of single body areas to general multi-system or complete single organ system examinations.

•*DG: Specific abnormal and relevant negative findings of the examination of the affected or symptomatic body area(s) or organ system(s) should be documented. A notation of "abnormal" without elaboration is insufficient.*

•*DG: Abnormal or unexpected findings of the examination of the unaffected or asymptomatic body area(s) or organ system(s) should be described.*

•*DG: A brief statement or notation indicating "negative" or "normal" is sufficient to document normal findings related to unaffected area(s) or asymptomatic organ system(s).*

•*DG: The medical record for a general multi-system examination should include findings about 8 or more of the 12 organ systems.*

C. DOCUMENTATION OF THE COMPLEXITY OF MEDICAL DECISION MAKING

The levels of E/M services recognize four types of medical decision making (straight-forward, low complexity, moderate complexity and high complexity). Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by:

- the number of possible diagnoses and/or the number of management options that must be considered;
- the amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed and analyzed; and
- the risk of significant complications, morbidity and/or mortality, as well as comorbidities, associated with the patient's presenting problem(s), the diagnostic procedure(s) and/or the possible management options.

The chart below shows the progression of the elements required for each level of medical decision making. To qualify for a given type of decision making, **two of the three elements in the table must be either met or exceeded.**

NUMBER OF DIAGNOSES OR MANAGEMENT OPTIONS

The number of possible diagnoses and/or the number of management options that must be considered is based on the number and types of problems addressed during the encounter, the complexity of establishing a diagnosis and the management decisions that are made by the physician.

Generally, decision making with respect to a diagnosed problem is easier than that for an identified but undiagnosed problem. The number and type of diagnostic tests employed may be an indicator of the number of possible diagnoses. Problems which are improving or resolving are less complex than those which are worsening or failing to change as expected. The need to seek advice from others is another indicator of complexity of diagnostic or management problems.

•*DG: For each encounter, an assessment, clinical impression, or diagnosis should be documented. It may be explicitly stated or implied in documented decisions regarding management plans and/or further evaluation.*

- For a presenting problem with an established diagnosis the record should reflect whether the problem is: a) improved, well controlled, resolving or resolved; or, b) inadequately controlled, worsening, or failing to change as expected.
- For a presenting problem without an established diagnosis, the assessment or clinical impression may be stated in the form of a differential diagnoses or as "possible", probable", or "rule out" (R/O) diagnoses.

Number of diagnoses or management options	Amount and/or complexity of data to be reviewed	Risk of complications and/or morbidity mortality	Type of decision making
Minimal	Minimal or None	Minimal	**Straight forward**
Limited	Limited	Low	**Low Complexity**
Multiple	Moderate	Moderate	**Moderate Complexity**
Extensive	Extensive	High	**High Complexity**

Each of the elements of medical decision making is described.

- *•DG: The initiation of, or changes in, treatment should be documented. Treatment includes a wide range of management options including patient instructions, nursing instructions, therapies, and medications.*
- *•DG: If referrals are made, consultations requested or advice sought, the record should indicate to whom or where the referral or consultation is made or from whom the advice is requested.*

AMOUNT AND/OR COMPLEXITY OF DATA TO BE REVIEWED

The amount and complexity of data to be reviewed is based on the types of diagnostic testing ordered or reviewed. A decision to obtain and review old medical records and/or obtain history from sources other than the patient increases the amount and complexity of data to be reviewed.

Discussion of contradictory or unexpected test results with the physician who performed or interpreted the test is an indication of the complexity of data being reviewed. On occasion the physician who ordered a test may personally review the image, tracing or specimen to supplement information from the physician who prepared the test report or interpretation; this is another indication of the complexity of data being reviewed.

- *•DG: If a diagnostic service (test or procedure) is ordered, planned, scheduled, or performed at the time of the E/M encounter, the type of service, eg, lab or x-ray, should be documented.*
- *•DG: The review of lab, radiology and/or other diagnostic tests should be documented. An entry in a progress note such as "WBC elevated" or "chest x-ray unremarkable" is acceptable. Alternatively, the review may be documented by initialing and dating the report containing the test results.*
- *•DG: A decision to obtain old records or decision to obtain additional history from the family, caretaker or other source to supplement that obtained from the patient should be* documented.
- *•DG: Relevant findings from the review of old records and/or the receipt of additional history from the family, caretaker or other source should be documented. A notation of "old records reviewed'" or "additional history obtained from family" without elaboration is insufficient.*
- *•DG: The results of discussion of laboratory, radiology or other diagnostic tests with the physician who performed or interpreted the study should be documented.*
- *•DG: The direct visualization and independent interpretation of an image, tracing or specimen previously or subsequently interpreted by another physician should be documented.*

RISK OF SIGNIFICANT COMPLICATIONS, MORBIDITY, AND/OR MORTALITY

The risk of significant complications, morbidity, and/or mortality is based on the risks associated with the presenting problem(s), the diagnostic procedure(s), and the possible management options.

- *•DG: Comorbidities/underlying diseases or other factors that increase the complexity of medical decision making by increasing the risk of complications, morbidity, and/or mortality should be documented.*
- *•DG: If a surgical or invasive diagnostic procedure is ordered, planned or scheduled at the time of the E/M encounter, the type of procedure, eg, laparoscopy, should be documented.*
- *•DG: If a surgical or invasive diagnostic procedure is performed at the time of the E/M encounter, the specific procedure should be documented.*
- *•DG: The referral for or decision to perform a surgical or invasive diagnostic procedure on an urgent basis should be documented or implied.*

The following table may be used to help determine whether the risk of significant complications, morbidity, and/or mortality is **minimal, low, moderate**, or **high**. Because the determination of risk is complex and not readily quantifiable, the table includes common clinical examples rather than absolute measures of risk. The assessment of risk of the presenting problem(s) is based on the risk related to the disease process anticipated between the present encounter and the next one. The assessment of risk of selecting diagnostic procedures and management options is based on the risk during and immediately following any procedures or treatment. The highest level of risk in any one category (presenting problem(s), diagnostic procedure(s), or management options) determines the overall risk.

TABLE OF RISK

Level of Risk	Presenting Problem(s)	Diagnostic Procedure(s) Ordered	Management Options Selected
Minimal	• One self-limited or minor problem, eg cold, insect bite, tinea corporis	• Laboratory tests requiring venipuncture • Chest x-rays • EKG/EEG • Urinalysis • Ultrasound, eg, echocardiography • KOH prep	• Rest • Gargles • Elastic bandages • Superficial dressings
Low	• Two or more self-limited or minor problems • One stable chronic illness, eg well controlled hypertension or non-insulin dependent diabetes, cataract, BPH • Acute uncomplicated illness or injury, eg, cystitis, allergic rhinitis, simple sprain	• Physiologic tests not under stress, eg, pulmonary function tests • Non-cardiovascular imaging studies with contrast, eg, barium enema • Superficial needle biopsies • Clinical laboratory tests requiring arterial puncture • Skin biopsies	• Over-the-counter drugs • Minor surgery with no identified risk factors • Physical therapy • Occupational therapy • IV fluids without additives
Moderate	• One or more chronic illnesses with mild exacerbation, progression, or side effects of treatment • Two or more stable chronic illnesses • Undiagnosed new problem with uncertain prognosis, eg, lump in breast • Acute illness with systemic symptoms, eg, pyelonephritis, pneumonitis, colitis • Acute complicated injury, eg head injury with brief loss of consciousness	• Physiologic tests under stress, eg, cardiac stress test, fetal contraction stress test • Diagnostic endoscopies with no identified risk factors • Deep needle or incisional biopsy • Cardiovascular imaging studies with contrast and no identified risk factors, eg arteriogram, cardiac catheterization • Obtain fluid from body cavity, eg lumbar puncture, thoracentesis, culdocentesis	• Minor surgery with identified risk factors • Elective major surgery (open, percutaneous or endoscopic) with no identified risk factors • Prescription drug management • Therapeutic nuclear medicine • IV fluids with additives • Closed treatment of fracture or dislocation without manipulation
High	• One or more chronic illnesses with severe exacerbation, progression, or side effects of treatment • Acute or chronic illnesses or injuries that may pose a threat to life or bodily function, eg multiple trauma, acute MI, pulmonary embolus, severe respiratory distress, progressive severe rheumatoid arthritis, psychiatric illness with potential threat to self or others, peritonitis, acute renal failure • An abrupt change in neurologic status, eg seizure, TIA, weakness, or sensory loss	• Cardiovascular imaging studies with contrast with identified risk factors • Cardiac electrophysiological tests • Diagnostic Endoscopies with identified risk factors • Discography	• Elective major surgery (open, percutaneous or endoscopic) with identified risk factors • Emergency major surgery (open, percutaneous or endoscopic) • Parenteral controlled substances • Drug therapy requiring intensive monitoring for toxicity • Decision not to resuscitate or to de-escalate care because of poor prognosis

D. DOCUMENTATION OF AN ENCOUNTER DOMINATED BY COUNSELING OR COORDINATION OF CARE

In the case where counseling and/or coordination of care dominates (more than 50%) of the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.

•*DG: If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.*

IV. ASSIGNING THE APPROPRIATE E/M CODE: PHYSICIAN SERVICE AND MEDICAL REVIEW

The following table is a convenient reference for the physician's assignment of the proper E/M service code. Medicare will also use this table as a reference for reviewing physician billing.

How to use the table:

From the documentation in the medical record, circle the most appropriate description of each key component History, Examination, and Decision Making. Only one description per row should be circled.

If a column has 2 or 3 circles, draw a line down that column to the bottom row and circle the code.

Otherwise, find the column with the 2nd circle from left to right. Draw a line down that column to the bottom row and circle the code. The circled code is the proper CPT code to report based on the documentation.

Reference table for assigning proper CPT Code for E/M service.

History	Not Applicable	Problem, Focused History	Expanded Problem Focused History	Detailed History	Comprehensive History
Examination	Not Applicable	Problem Focused Exam	Expanded Problem Focused Exam	Detailed Exam	Comprehensive Exam
Decision Making	Not Applicable	Straight Forward	Low Complexity	Moderate Complexity	High Complexity
Code	99211	99212	99213	99214	99215

The Alabama Infected Health Care Worker Act

State Department of Public Health

Alabama's Infected Health Care Worker Management Act is now in effect. Public Law #102-141, Section 633 became effective on October 28, 1991, requiring all states to adopt the Centers for Disease Control and Prevention (CDC) Recommendations (or the equivalent) for preventing transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to patients during Exposure-Prone Invasive Procedures.[1] Compliance of such became the responsibility of each state's public health officer.

On August 24, 1993, Alabama's Governor, Jim Folsom, Jr., signed into law the Alabama Infected Health Care Worker Management Act. On November 16, 1994, the State Committee of Public Health approved a set of rules to regulate how the act will be implemented.

The purpose of the Act is to prevent transmission of HIV and HBV to patients during invasive procedures. According to the CDC, current data suggest that the risk for such transmission from a health care worker (HCW) to a patient during an invasive procedure is small; a precise assessment of the risk is not yet available.

The Act mandates that any HCW infected with HIV or HBV who performs an invasive procedure or any physician providing care to an infected HCW shall notify the State Health Officer, or his designee, of the infection.

For clarification and continuity purposes, the following words have the following meanings:

(1) **HEALTH CARE WORKER**. Physicians, dentists, nurses, respiratory therapists, phlebotomists, surgical technicians, physician assistants, podiatrists, dialysis technicians, emergency medical technicians, paramedics, ambulance drivers, dental hygienists, dental assistants, students in the healing arts, or any other individual who provides or assists in the provision of medical, dental, or nursing services.

(2) **INFECTED HEALTH CARE WORKER**. A health care worker infected with HIV or HBV as defined herein.

(3) **HEPATITIS B VIRUS (HBV) INFECTION**. The presence of the HBV as determined by the presence of hepatitis B(e) antigen for six months or longer or by other means as determined by the State Board of Health.

(4) **HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION**. The presence of antibodies to Human Immunodeficiency Virus as determined by enzyme immunoassay and Western Blot or the presence of the HIV infection as determined by viral culture, or by other means as determined by the State Board of Health.

(5) **INVASIVE PROCEDURES**. (a) Those medical or surgical procedures characterized by the digital palpation of a needle tip in a body cavity or by the simultaneous presence of the health care worker's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site.

(b) Invasive dental procedures shall include those that provide the opportunity for an intraoral percutaneous injury to the dental health care worker and could result in the blood of-the health care worker coming in contact with the blood or mucous membrane of the patient.

Upon receipt of a report of an infected HCW, an internal department review of his/her practices will be performed to determine if invasive procedures are being performed. If it is determined that they are being performed, the State Health Officer shall, as the situation requires, issue orders temporarily limiting the infected HCW's practice of performing invasive procedures, since such could constitute a direct threat to the patients he/she is serving. An expert review panel will be formed to review the overall practice and procedures of the infected HCW. Based upon the panel's findings of fact and recommendations, the State Health Officer may issue restrictions on the practice of the worker.

Other components of the Act include:

- provision of an appeal process for the infected HCW;
- authorization of monitoring of the health care worker's practice with required reporting of violations to the State Health Officer;

- provision of grounds for revocation, suspension, or restriction of infected HCWs licensed by licensing boards;
- creation of confidentiality standards; and
- provision of penalties for violations of the Act.

Previous investigations of HIV and HBV transmission from HCWs to patients have found that when HCWs adhere to recommended infection control procedures, the risk of transmitting HBV from an HCW to a patient is small, and the risk of transmitting HIV is even smaller. All HCWs should adhere to universal precautions and handle the blood and other specified body fluids of all patients as if they are infectious for HIV, HBV, or other bloodborne pathogens. Emphasis should be placed on appropriate use of handwashing, protective barriers, and care in the use and disposal of needles and other sharps.

The Alabama Department of Public Health will be working with the individual medical and dental licensing boards (Board of Medical Examiners, Board of Nursing, Board of Dental Examiners, etc.) and various health-related associations (Medical Association of the State of Alabama, Alabama State Nurses Association, Alabama Dental Association, Alabama Hospital Association, Alabama Nursing Home Association, etc.) to disseminate information concerning the rules and regulations.

Additional information is available from the Alabama Department of Public Health, Division of Infection Control, Montgomery, 334/613-5325.

Charlotte Crysel, RN, BSN Director
Division of Infection Control
Bureau of Disease Control
Alabama Department of Public Health

1. CDC. Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure - Prone Invasive Procedures. MMWR 1991; 40 (Suppl. no RR-8).

Rules of the State Board of Health For Infected Health Care Workers

420-4-3-.01 Purpose
420-4-3-.02 Definitions
420-4-3-.03 Implementation of Public Law and Recommendations: Assistance to Licensing Boards; Records
420-4-3-.04 Reporting
420-4-3-.05 Internal Department Review
420-4-3-.06 Expert Review Panel
420-4-3-.07 Review Practice and Procedure and Subpoena Forms
420-4-3-.08 Final Orders
420-4-3-.09 Appeals
420-4-3-.10 Verification and Documentation
420-4-3-.11 Disciplinary Action
420-4-3-.12 Confidentiality

420-4-3-.01 Purpose.

The purpose of the Chapter is to provide for administration and implementation of the "Infected Health Care Worker Management Act" (IHCWMA) to prevent transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to patients during invasive procedures.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.

History:

420-4-3-.02 Definitions.

When used herein, the following words and terms shall have the meanings respectively ascribed to them except where the context prohibits.

(a) "CDC" means the Centers for Disease Control and Prevention of the United States Public Health Service.

(b) "CDC Recommendations" means the July 21, 1991, CDC document (MMWR, Volume 40. No. RR-8) entitled "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures" or equivalent guidelines developed by the Alabama Department of Public Health and approved by the CDC and any appropriate supplements or revisions thereto.

(c) "Department" means the Alabama Department of Public Health.

(d) "Expert review panel" (ERP) means a panel of

experts in composition and function as defined in the CDC recommendations and appointed or approved by the Department.

(e) "Health Care Worker" (HCW) means any individual who provides or assists in the provision of medical, dental or nursing services regardless of whether that individual is formally licensed.

(f) "Hepatitis B virus Infection" (HBV) means the presence of the hepatitis B virus as determined by the presence of hepatitis B e antigen for six months or longer or by other means as determined by the State Board of Health.

(g) "HIV Infection" (HIV) means the presence of antibodies to the Human Immunodeficiency virus as determined by enzyme immunoassay and Western Blot, the presence of the Human Immunodeficiency Virus as determined by viral culture, or other means determined by the State Board of Health.

(h) "Infected health care worker" (IHCW) means any HCW as defined in (e) who is infected with HIV or HBV as defined in (f) and (g).

(i) Internal Department Review" means investigation by Department staff with advice and consultation of individuals and organizations with expertise in a specified discipline to determine if an IHCW performs lnvasive procedures.

(j) "Invasive Procedures" include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site.

(1) Invasive dental procedures shall include those that provide the opportunity for an intraoral percutaneous injury to the dental HCW and could result in the blood of the HCW coming in contact with the blood or mucous membrane of the patient as adopted by the Board of Dental Examiners in rules developed pursuant to Section 11.

(2) These procedures shall not include physical examinations; blood pressure checks; eye examinations; phlebotomy; administering intramuscular, intradermal, or subcutaneous injections; needle biopsies; needle aspirations; lumbar punctures; angiographic procedures; vaginal, oral, or rectal exams; endoscopic or bronchoscopic procedures; or placing and maintaining peripheral and central intravascular lines, nasogastric tubes, endotracheal tubes, rectal tubes, and urinary catheters.

(k) "Licensing Board" means the health professional licensing boards which are state agencies and which license and regulate specific HCWs such as the Board of Medical Examiners, the Medical Licensure Commission, the Board of Nursing, the Board of Dental Examiners and the Board of Podiatry.

(l) Public law" means Public Law 102-141, Section 633, enacted October 28, 1991.

(m) "State Health Officer" as defined in the Code of Alabama 1975, Chapter 2, Section 22-2-8.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.

History:

420-4-3-.03 Implementation of PL 102-141, Sec. 633, and CDC Recommendations; Assistance to Licensing Boards; Provision of Records.

(a) The Department is authorized to enforce compliance and oversee the implementation of the Public Law and applicable CDC recommendations and any appropriate supplements and revisions to the CDC recommendations which apply to HCWS.

(b) The Department shall provide consultation and assistance to licensing boards, as appropriate, to ensure compliance with CDC recommendations.

(c) Any IHCW shall make available to the Department all records requested by the Department and shall cooperate fully with the Department in the investigation.

(d) Any person having knowledge of an IHCW, the administrator of any health care facility having knowledge of any IHCW, any person serving as guardian of or the conservator, administrator or executor of the estate or agent or representative of any IHCW or any person serving as the custodian of records of the patients of any IHCW or facility employing such worker shall provide in the manner requested by the State Health Officer (SHO) to the Department all requested documents and information and shall cooperate fully with the Department in any investigation.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6),22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70

History:

420-4-3-.04 Reporting.

(a) Any IHCW who performs invasive procedures as defined herein shall notify the designee of the SHO by sending a letter marked "Personal and Confidential" to the Director of the Division of Infection Control within 30 days of the time he or she is aware of his or her infection. The letter shall include at a minimum the IHCW's name and diagnosis and information as to how he or she can be contacted. The IHCW shall subsequently make available to the Department all requested documents or records three years old or less and shall cooperate fully with the Department in the investigation. It shall be grounds for revocation, suspension, or restriction of the professional license of any licensed IHCW who shall be found to perform invasive procedures and shall have failed to notify the SHO .

(b) Any physician providing care to any IHCW shall notify the SHO of the infected status of his patient within seven (7) days of the time he or she diagnoses or provides such care. Such notification shall be on forms as designated by the Department and sent to the designee of the SHO by marking the envelope "Personal and Confidential" and sending it to the Director of the Division of Infection Control. (See report form, Appendix 1, which is attached.) Further, the physician shall make available to the Department all requested documents or records three years old or less and shall cooperate fully with the Department in the investigation.

(c) After reporting to the SHO, no IHCW shall perform or assist in performance of an invasive procedure, as defined in (j) above, until after an internal Department review by Department staff and written notification regarding conditions of practice from the SHO.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health
Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14(g), and 22-11A-70.
History:

420-4-3-.05 Internal Department Review.

The internal Department review will confirm the diagnosis and determine if invasive procedures are being performed.

(a) If the IHCW is determined NOT to perform invasive procedures, a letter will be sent to him or her stating the following information:

(1) No review panel shall be established.

(2) No restrictions shall be placed on his or her practice.

(3) All information obtained in the investigation shall be confidential as provided for in Section 10 of the IHCWMA.

(4) Should his or her job duties change at any time requiring invasive procedures to be performed, he or she shall by law (Sections 3 and 13 of the IHCWMA) notify the SHO prior to performing or assisting in the performance of an invasive procedure.

(5) Upon notification by the HCW of job duty changes, a new internal review will be conducted and actions taken according to new findings. The IHCW shall agree to cooperate with any investigation authorized in Section 4 of the IHCWMA and any necessary practice modification.

(b) If the IHCW IS determined to perform invasive procedures, the SHO shall cause an expert review panel to be formed. The SHO shall, as the situation requires, issue orders temporarily limiting the IHCW's practice as to performing invasive procedures since such could constitute a direct threat to the patients he (or she) is serving. The IHCW shall comply with such orders.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health
Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.
History:

420-4-3-.06 Expert Review Panel (ERP).

(a) The SHO shall cause an ERP to be formed if the IHCW is determined by internal Department review to perform invasive procedures.

(b) The ERP may include the physician of the IHCW and shall include the following by appointment of the SHO:

(1) One Alabama licensed physician with expertise in infectious diseases other than the one providing care to the IHCW.

(2) One additional Alabama licensed public health physician.

(3) Two representatives of the relevant licensing board.

(4) One HCW with expertise in procedures performed by the IHCW, selected by the licensing board of the HCW, if licensed.

(5) One representative of the employing institution(s) appointed by the employing institution(s), if applicable.

(6) Other individuals as deemed necessary.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health
Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.
History:

420-4-3-.07 Review Practice and Procedure and Subpoena Forms.

(a) The ERP shall review the overall practice and procedures performed by the IHCW by considering:

(1) the procedures performed by the IHCW;

(2) the adherence to universal precautions by the IHCW;

(3) the past history of the HCW of occupational injury while performing the invasive procedures;

(4) any prior evidence of the HCW related to patient transmission of HIV or HBV;

(5) the presence of conditions such as dermatitis, dementia, neuropathy, or other conditions that may increase the risk of transmission of HIV or HBV; and

(6) current CDC guidelines on the management of IHCWS.

(b) Subsequent recommendations shall be made to the SHO within 30 days of convening concerning:

(1) limitations on the performance of invasive procedures by the IHCW; and

(2) the need to notify patients who previously may have had an invasive procedure performed by the IHCW. The provider will be responsible for notifying such patients and will then certify to the Alabama Department of Public Health that such has been accomplished.

(c) Reviews by an ERP shall be conducted in an informal manner without the application of strict rules of evidence. The presiding officer shall have the responsibility for executing the procedures required to make a determination.

(d) Reviews before an ERP shall not be open to the public and the findings thereof shall be confidential.

(e) After reviewing the evidence the ERP shall make necessary findings of fact and recommendations to the SHO. Such recommendations shall be made by majority vote of the ERP with concurring or dissenting opinions noted and reported with the reasons therefor.

(f) The majority finding and recommendation with all dissenting or concurring opinions shall be compiled and signed by the presiding officer noting the vote on such and reported to the SHO.

Author: John Wible, General Counsel, Alabama Department of Public Health
Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.
History:

420-4-3-.08 Final Order of the State Health Officer;

Notification of Individuals and Institutions or Licensing Boards.

After receiving recommendations from the ERP, the SHO shall make a determination and will provide written notification specifying restrictions, limitations, conditions, or prohibitions on the practice of the IHCW to:

(a) the IHCW;

(b) the administrator of the employing institution;

(c) the employer of the IHCW; and

(d) the appropriate licensing board.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health
Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70. History:

420-4-3-.09 Appeal Process, Procedure and Forms.

(a) An IHCW may appeal the final order of the SHO to the State Committee of Public Health (SCPH) by delivery of written notice of appeal to the SHO not more than 30 days after the date of the SHO's final order. The appeal shall be heard by an administrative law judge or hearing officer, appointed by the SHO, for trial and recommended decision. All such hearings shall be conducted in accordance with Alabama Administrative Code, Chapter 420-1-3, et seq.

(b) The Hearing Officer shall make Findings of Fact, Conclusions of Law, and Recommendations to the SCPH which shall review same en banc along with the record and shall issue a final order signed by the Chairman.

(c) An IHCW or any party as defined by Alabama Administrative Code, Chapter 420-1-3 who is aggrieved by the outcome of appeal to the SCPH may file notice of further appeal in accordance with the "Alabama Administrative Procedures Act" in the circuit court of his or her coun-

ty of residence or in the Circuit Court of Montgomery County within 30 days of issuance of final decision of the SCPH.

Author: John Wible, General Counsel, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70

History:

420-4-3-.10 Verification and Documentation of IHCW Compliance with Restrictions, Limitations or Conditions of Practice of IHCW.

(a) If no limitations were imposed, the practice of the IHCW will be reviewed annually by internal Department review. If the review determines that practice restrictions may be necessary for an IHCW for whom practice restrictions were initially not necessary, the SHO shall convene an ERP.

(b) If limitations were previously determined to be necessary, the practice of the IHCW will be reviewed annually by internal Department review.

(1) If review determines noncompliance of practice restrictions, the SHO shall forward evidence of such noncompliance to the appropriate licensing board or to the employer of the IHCW if he or she does not have a professional license.

(2) If review determines that practice restrictions may be necessary for whom practice restrictions had not been previously necessary, the SHO shall convene an ERP.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.

History:

420-4-3-.11 Disciplinary Action for Violation of ERP Recommendations or Related Rule.

An IHCW who violates a recommendation of the ERP as set forth herein the related rules is subject to disciplinary action by the appropriate licensing board.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.

History:

420-4-3-.12 Confidentiality.

The records, proceedings, deliberations, and documents related to the investigation and review of any IHCW are confidential and shall be used by committees, licensing boards of licensed HCWs, panels, and individuals only in the exercise of their official duties and shall not be public records except as provided by law.

Author: Charlotte E. Crysel, Director, Division of Infection Control, Alabama Department of Public Health

Statutory Authority: Code of Alabama, 1975, Sections 22-2-2 (6), 22-11A-2, 22-11A-7, 22-11A-13, 22-11A-14 (g), and 22-11A-70.

History:

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Alabama Department of Public Health Policy and Procedures for Compliance With CDC Recommendations of July 12, 1991 and Alabama's Infected Health Care Worker Management Act

I. BACKGROUND

Public Law # 102-141, Section 633 became effective on October 28, 1991. This law requires that all states adopt the Centers for Disease Control and Prevention's (CDC) July, 1991, "Recommendations for Preventing Transmission of HIV and HBV to Patients During Exposure-Prone Invasive Procedures." This document serves as a guideline for all health care workers (HCWs), especially those infected with HIV and/or HBV and who perform invasive procedures in which there is the potential for the patient to be exposed to the worker's blood.

On August 24, 1993, Alabama's Governor, Jim Folsom, signed into law "The Alabama Infected Health Care Worker Management Act." This law requires reporting of an infected health care worker (IHCW) to the State Health Officer (SHO); requires an IHCW to submit to review by an expert review panel(ERP); authorizes the SHO to undertake a review of the practice of an IHCW to determine if invasive procedures are performed by the worker; authorizes the creation of expert review panels and provides for their composition and duties; authorizes the SHO to issue restrictions on the practice of the IHCW; provides for an appeal process; authorizes the monitoring of the practice of the IHCW and requires reporting of violations to the SHO; provides grounds for revocation, suspension, or restriction of IHCWs licensed by licensing boards; requires IHCWs and third parties with records or information to provide records or other information and to cooperate with an investigation; provides immunity from civil and criminal liability for individuals, agencies, experts, and committees involved in the investigation of an IHCW; creates confidentiality standards and provides for use of the information gained during an investigation; authorizes promulgation of rules by the Alabama Department of Public Health (ADPH) for administration of this act; enables the State Board of Health to file suit in circuit court to compel compliance; and provides penalties for violation of this law.

II. DEFINITIONS

A. CDC means the Centers for Disease Control and Prevention of the U.S. Public Health Service.

B. CDC Recommendations means the July 21, 1991, CDC document (MMWR, Volume 40. No. RR-8) entitled "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures" or equivalent guidelines developed by the Department and approved by the CDC and any appropriate supplements or revisions thereto.

C. Department means the Alabama Department of Public Health.

D. Expert review panel (ERP) means a panel of experts in composition and function as defined in the CDC recommendations and appointed or approved by the Department.

E. Health Care Worker (HCW) means any individual who provides or assists in the provision of medical, dental, or nursing services regardless of whether that individual is formally licensed or not.

F. Hepatitis B Virus Infection (HBV) means the presence of the hepatitis B virus as determined by the presence of the hepatitis B e antigen for six months or longer or by other means as determined by the State Board of Health.

G. HIV Infection (HIV) means the presence of antibodies to the Human Immunodeficiency Virus as determined by enzyme immunoassay and Western Blot, the presence of the Human Immunodeficiency Virus as determined by viral culture, or other means determined by the State Board of Health.

H. Infected health care worker (IHCW) means any HCW as defined in (E) who is infected with HIV or HBV as defined in F and G.

I. Internal Department Review means investigation by Department staff with advice and consultation of individuals and organizations with expertise in a specified discipline to determine if an IHCW performs invasive procedures.

J. Invasive Procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW'S fingers and needle tip in a body cavity or the simultaneous pres-

ence of the HCW's fingers and needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site.

(1) Invasive dental procedures shall include those that provide the opportunity for an intraoral percutaneous injury to the dental HCW and could result in the blood of the HCW coming in contact with the blood or mucous membrane of the patient as adopted by the Board of Dental Examiners.

(2) These procedures shall not include physical examinations; blood pressure checks; eye examinations; phlebotomy; administering intramuscular, intradermal, or subcutaneous injections; needle biopsies; needle aspirations; lumbar punctures; angiographic procedures; vaginal, oral, or rectal exams; endoscopic or bronchoscopic procedures; or placing and maintaining peripheral and central intravascular lines, nasogastric tubes, endotracheal tubes, rectal tubes, and urinary catheters.

K. Licensing board means the health professional licensing boards which are state agencies and which license and regulate specific health care workers such as the Board of Medical Examiners, the Medical Licensure Commission, the Board of Nursing, the Board of Dental Examiners and the Board of Podiatry.

L. Public Law means Public Law 102-141, Section 633, enacted October 28, 1991.

M. State Health Officer as defined in the Code of Alabama 1975, Chapter 2, Section 22-2-8.

III. ADPH POLICY STATEMENT

The Alabama Department of Public Health will comply with the Public Law #102-141, Section 633 and "The Alabama Infected Health Care Worker Management Act." Responsibility for relevant program development, organization and implementation and compliance with the law will rest within the Division of Infection Control, Bureau of Disease Control.

IV. ADPH PROCEDURES FOR ASSESSMENT AND PRACTICE MANAGEMENT OF INFECTED HEALTH CARE WORKERS (IHCWs)

A. REPORTING SOURCES

1. Any IHCW who performs invasive procedures as defined herein shall notify the designee of the SHO by sending a letter marked "Personal and Confidential" to the Director of the Division of Infection Control within 30 days of the time he/she is aware of his/her infection. The letter shall include at a minimum the IHCW's name and diagnosis and information as to how he/she can be contacted. The IHCW shall subsequently make available to the Department all records requested by the Department and shall cooperate fully with the Department in any investigation.

2. Any physician providing care to any IHCW, shall notify the SHO of the infected status of his/her patient, within seven (7) days of the time he/she diagnoses or provides such care. Such notification shall be on forms as designated by the Department and are to be sent to the designee of the SHO by marking the envelope "Personal and Confidential" and sending it to the Director of the Division of Infection Control. (See report form Appendix 2 which is attached.) Further, the physician shall make available to the Department all records requested by the Department and shall cooperate fully with the Department in any investigation.

B. INTERNAL DEPARTMENT REVIEW

Any HIV or HBV IHCW reported to the SHO from sources as outlined in Section IV-A of this document will be investigated by an internal Department review to determine if the IHCW performs invasive procedures.

The Department review team will include staff from the Division of Infection Control, Division of HIV/AIDS Prevention and Control, and the Division of Epidemiology. The team may consult with individuals and organizations with expertise in the HCW's specific discipline and individuals who have directly observed the HCW's performance in his/her practice.

1. Guidelines for investigation
 a. Interview with IHCW.
 b. On-site review of practice of IHCW including patient record review.
2. Results of investigation
 a. IHCW determined NOT to perform invasive procedures:
 (1) No Expert Review Panel (ERP) convened.
 (2) No limitation on practice.
 (3) IHCW to self-report (by law) future performance of invasive procedures.
 (4) Information in confidential file.
 (5) Notification of IHCW of results of investigation.
 b. IHCW DOES perform invasive procedures:

(1) SHO convenes ERP

and

(2) As required, isues orders temporarily limiting IHCW'S practice.

C. EXPERT REVIEW PANEL

1. If a HCW infected with HIV or HBV is determined by the internal Department review to perform invasive procedures, the SHO will convene an ERP within 30 days of the determination.
2. To the extent possible the review shall be conducted so that the identity of the HCW shall not be disclosed to the ERP.
3. The ERP may include the physician of the IHCW and shall include the following by appointment of the SHO:
 a. One Alabama licensed physician with expertise in infectious diseases other than one providing care to the IHCW.
 b. One additional Alabama licensed public health physician.
 c. Two representatives of the relevant licensing board.
 d. One HCW with expertise in procedures performed by the IHCW selected by the licensing board of the IHCW, if licensed.
 e. One representative of the employing institution(s) appointed by the employing institution(s), if applicable.
 f. Other individuals as deemed necessary.
4. Reviews by an ERP shall be conducted in an informal manner without the application of strict rules of evidence. The presiding officer shall have the responsibility for executing the procedures required to make a determination.
5. Reviews before an ERP shall not be open to the public and the findings thereof shall be confidential.
6. The IHCW is entitled to be present at meetings of the ERP and to present any information pertinent to the panel deliberations.

D. REVIEW OF PRACTICE AND PROCEDURES BY ERP

1. The ERP shall review the overall practice and procedures performed by the IHCW by considering: a. the procedures performed by the IHCW. The performance of invasive procedures alone shall not present sufficient cause to limit his or her practice.
 b. the adherence to universal precautions by the IHCW;
 c. the past history of the HCW of occupational injury while performing the invasive procedures;
 d. any prior evidence of the HCW related to patient transmission of HIV or HBV;
 e. the presence of conditions such as dermatitis, dementia, neuropathy, or other conditions that may increase the risk of transmission of HIV or HBV; and
 f. current CDC guidelines on the management of IHCWS.
2. After reviewing the evidence, the ERP shall make necessary finding of fact and recommendations to the SHO. Such recommendations shall be made by majority vote of the ERP with concurring or dissenting opinions noted and reported with the reasons thereof.
3. Subsequent recommendations shall be made to the SHO wi thin 30 days of convening concerning: a. limitations on the performance of invasive procedures by the IHCW; and
 b. the need to notify patients who previously may have had an invasive procedure performed by the IHCW. The provider will be responsible for notifying such patients and will then certify to the Alabama Department of Public Health that such has been accomplished.

V. FINAL ORDER OF SHO

After receiving recommendations from the ERP, the SHO shall make a determination and will provide within 30 days, written notification specifying restrictions, limitations, conditions, or prohibitions on the practice of the IHCW.

A. **<u>NO Restrictions Imposed by the ERP:</u>**

1. IHCW to self-report any changes in his or her work practice.
2. Annual internal Department reviews will be performed and follow-up will be based upon findings:
 a. No invasive procedures found to be performed
 (1) Investigation information sent to:
 (a) IHCW
 (b) Institution(s)
 (c) Employer
 (d) Licensing Board (if applicable)
 (2) Annual internal Department review will be performed.
 b. <u>Invasive Procedures found to be performed</u>

 SHO convenes an ERP (See Section IV-D

"Review of Practice and Procedures by ERP").

B. Restrictions Imposed bY the ERP

1. Within 30 days of issuance of the restrictions the SHO will notify the following:
 a. IHCW
 b. Institution(s)
 c. Employer
 d. Licensing 80ard (if applicable)
2. Annual internal Department reviews will be performed and follow-up based upon findings:
 a. If IHCW found to be compliant with restrictions:
 (1) Investigation information will be sent to:
 (a) IHCW
 (b) Institution(s)
 (c) Employer
 (d) Licensing Board (if applicable)
 (2) Annual internal Department reviews.
 b. If IHCW found to be non-compliant with restrictions:

Violations will be reported to appropriate licensing board (if applicable) or to employer of the IHCW for disciplinary action.

VI. APPEAL PROCESS

A. Final order of SHO may be appealed to State Committee of Public Health (SCPH) by delivery of notice of appeal within 30 days after date of final order.

B. Appeal may be heard by SCPH or may be assigned to administrative law judge or hearing officer.

C. IHCW who is aggrieved by outcome of appeal to SCPH may file notice of further appeal in the circuit court of his or her county of residence or in the Circuit Court of Montgomery County within 30 days of the issuance of the final decision of the SCPH.

D. The Alabama Supreme Court shall issue any additional rules it deems necessary to assure that appeals under this section are handled in a confidential and anonymous manner.



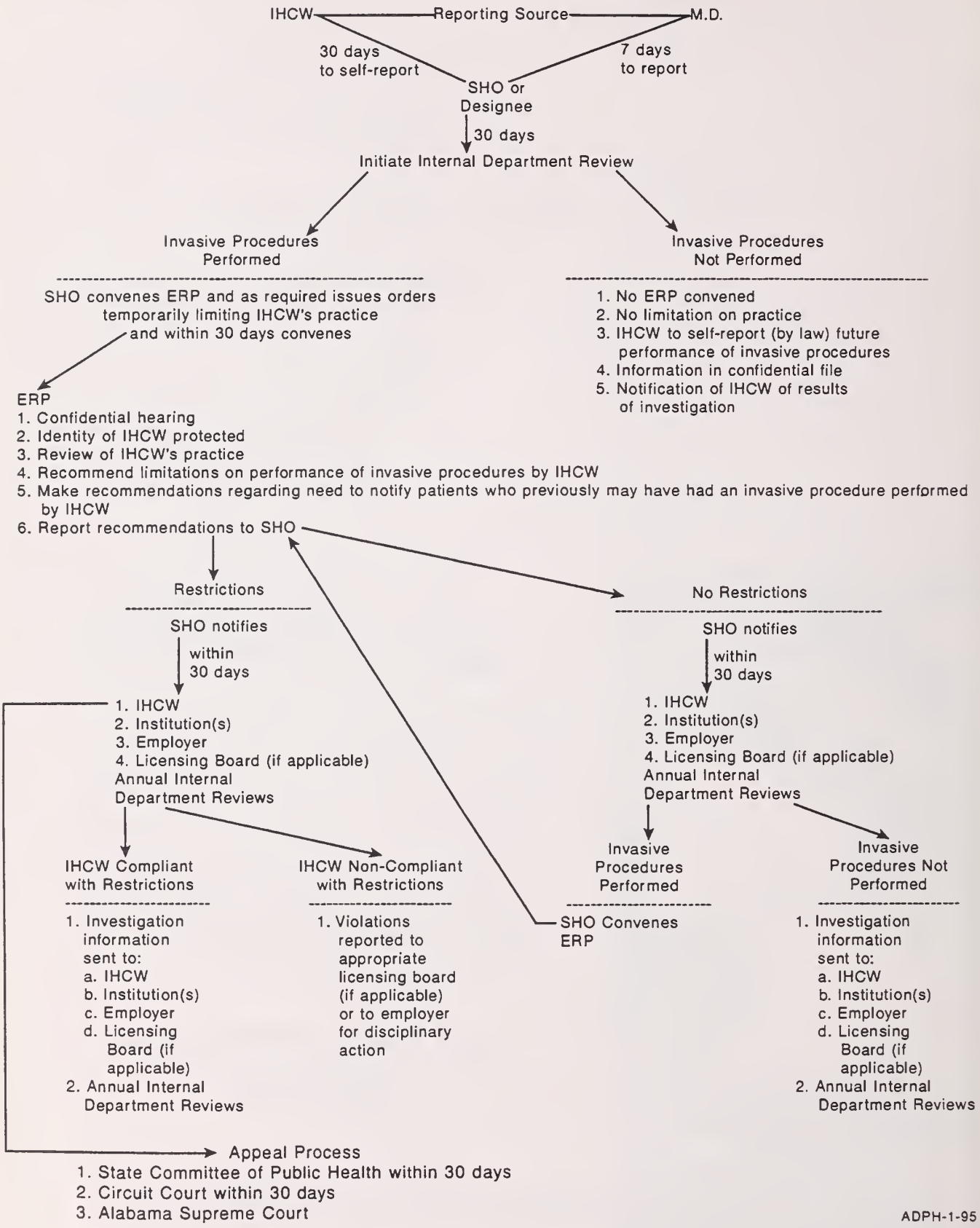
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ALABAMA PROCEDURES FOR ASSESSMENT AND PRACTICE MANAGEMENT OF HBV AND HIV-INFECTED HEALTH CARE WORKERS (HCWs)
FLOW CHART OF PROCEDURES



ADPH-1-95

APPENDIX 1

ALABAMA DEPARTMENT OF PUBLIC HEALTH
PHYSICIAN'S NOTIFICATION OF
HIV AND/OR HBV INFECTED HEALTH CARE WORKER

Information: The Infected Health Care Worker Management Act was signed into law on August 24, 1993). The purpose of the law is to prevent transmission of the Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) from infected health care workers (IHCWs) to patients during the performance of exposure-prone invasive procedures. HBV infection is defined as the presence of the Hepatitis B e antigen for six months or longer. The law mandates "Any physician providing care to an infected health care worker shall notify the State Health Officer about the presence of the infection in the health care worker in a time and manner prescribed by the State Board of Health."

(SEE INSTRUCTION ON NEXT PAGE FOR COMPLETING AND MAILING REPORT)

I. PATIENT INFORMATION:

Name: _____ Sex: ____ Female ____ Male

Address: _____

Home Phone: _____ Work Phone: _____

Date of Birth: _____ Social Security Number: _____

II. EMPLOYMENT INFOMATION:

Occupation: _____

Name of Employer: _____

Address of Employer: _____

III. MEDICAL INFORMATION:

A. DIAGNOSIS:

1) HIV Positive: _____ Yes _____ No

Date of Enzyme Immunocassay (EIA): _____

Date of Western Blot: _____

2) Hepatitis B e Antigen Positive: _____ Yes _____ No

#1 Test Date: _____

#2 Test Date: _____

B. PRESENCE OF SYMPTONS OR CONDITIONS:

_____ Dementia

_____ Dermatitis (Body Site:) _____

_____ Neuropathy

_____ Others (Please List): _____

C. PAST HISTORY OF OCCUPATIONAL INJURY TO THE IHCW WHILE PERFORMING INVASTIVE PROCEDURES:

_____ Yes _____ No _____Don't Know

SUBMITTING PHYSICIAN: _____

_____ DATE: _____

PHONE: _____

INSTRUCTIONS: This form is to be completed and returned within seven (7) days of the time a diagnosis is made of HIV or Hepatitis B e Antigen positivity or provision of care of such. Completed forms are to be sent to the designee of the State Health Officer by marking the envelope "Personal and Confidential" and sending it to:

Director, Division of Infection Control
Alabama Department of Public Health
434 Monroe Street
Montgomery, Alabama 36130-3017

Invasive Procedures as defined in the Infected Health Care Worker Management Act are:

(1) Those medical or surgical procedures characterized by the digital palpation of a needle tip in a body cavity or by the simultaneous presence of the health care worker's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site.

(2) Invasive dental procedures shall include those that provide the opportunity for an intraoral percutaneous injury to the dental health care worker and could result in blood of the health care worker coming in contact with the blood or mucous membrane of the patient as adopted by the Board of Dental Examiners in rules developed pursuant to Section 11.

(3) These procedures shall not include physical examinations; blood pressure checks; eye examinations; phlebotomy; administering intramuscular, intradermal, or subcutaneous injections; needle aspirations; lumbar punctures; angiographic procedures; vaginal, oral, or rectal exams; endoscopic or bronchoscopic procedures; or placing and maintaining peripheral and central intravascular lines, nasogastric tubes, endotracheal tubes, rectal tubes, and urinary catheters.



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ALLIANCE: Body Trek

Donna Gosney — A-MASA President

Each year the American Medical Association Alliance recognizes outstanding health projects by awarding three HAP (Health Awareness Promotion) Awards. Alabama was very proud that one of these awards was given to Jefferson County Medical Auxiliary in recognition of Body Trek: A Journey Through Life, Diane Orso and Vina Morros accepted the award for Jefferson County at the 1994 AMAA Annual Convention. The following article was submitted by Jefferson County Medical Auxiliary.

Imagine for just a moment what it would be like to travel through the body and see how it functions! That's the unique opportunity children in the Birmingham-Jefferson County schools have as they experience BODY TREK *Journey Through Me.*

BODY TREK is a mobile health classroom where school children from Kindergarten through fifth grade learn about good health and about themselves. During a tour of this 48 foot traveling exhibit, children learn about bones and joints by watching a skeleton ride a bicycle; they touch a giant finger and learn about skin and the sense of touch; look through special eye glasses to experience the vision of a far-sighted and near-sighted person; and pump air into a giant set of lungs to see how they function. Children visiting the exhibit also learn the importance of "good fuel" as well as how "bad fuel" is harmful to the body. They can also pump "blood" through a gigantic heart and see how their food choices and other health decisions affect their hearts and health. Screenings on height, weight, and blood pressure are performed by trained volunteers.

BODY TREK is a cooperative educational program sponsored by the Jefferson County Medical Society, the Jefferson County Medical Auxiliary, The Children's Hospital of Alabama, and Blue Cross Blue Shield of Alabama. Since its beginning in 1992, approximately 13,000 students have had the opportunity to visit BODY TREK. During this school year, approximately 3750 students at twelve area schools will be participating in the program.

Any school, private or public in the Birmingham-Jefferson County area may request BODY TREK at no cost to the school. Certain requirements must be met for the schools to be eligible. Schools wishing to participate must provide: (1) a level, secured parking area for the trailer (2) electrical hook-up and (3) six parent volunteers a day. Parent participation is a very important component of this project. Information learned in the trailer can be re-enforced at home with help from the parents. Schools are scheduled according to the date of their request. BODY TREK is open Tuesday through Friday from 9:00-2:30 and is staffed by Auxiliary volunteers, parent volunteers, and one salaried coodinator.

The main goal of this project is to contribute to health awareness, health education and self responsibility for maintaining health. Healthy children become healthy adults and BODY TREK gets them started in the right direction.

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Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

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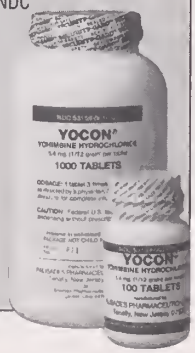
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



References:

1. A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month – day of month if weekly – and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

Illustrations: Illustrations should be numbered consecutively and indicated in the text. The number, indication of the top, and the author's name should be attached to the back of each illustration. Legend should be typed, numbered, and attached to each illustration. Photographs should be clear and distinct; drawings should be made in black ink on white paper. For photographs, glossy prints are preferred.

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Alabama Medicine

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DEMASSIFICATION?

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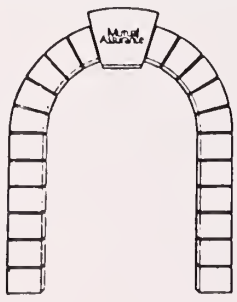
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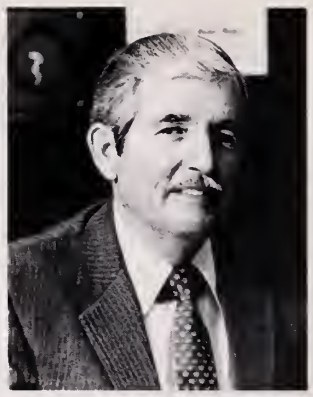
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S. Lon Conner
Executive Director, MASA

Here We Go Again

"The powers not delegated to the states by the Constitution, nor prohibited to the states, are reserved to the states respectively, or to the people."

10th Amendment
U.S. Constitution

Since I was a child "states rights" have been fighting words here in the South. Many of the elder generations had insisted that the Civil War was not fought over slavery but over the states' rights question; that the Solid South of legend was solidly Democratic for a greater part of this century because the Republican Party of Mr. Lincoln had opposed the South's state rights not only in the Civil War but in its aftermath, Reconstruction.

We Southerners quoted Jefferson – **our** kind of Democrat – in his writings favoring small and dispersed government. Until World War II, the South was an agrarian subcontinent and the Jeffersonian idea that virtue lived on the farms while evil thrived in the cities was entirely agreeable to us.

But no region had benefited more from the New Deal's redistribution of national wealth, as a Depression remedy, than the South. The entire nation was sorely beset between October 1929 and Pearl Harbor, but the South was devastated. Mr. Roosevelt's discovery that we Southerners were ill-housed, ill-clothed and ill-fed was resented by only a few because it was followed by various forms of rescue by the federal government.

That memory and the service of millions of Southerners in World War II, followed by the GI Bill, Hill-Burton, and various other forms of post war federal largesse, weakened our antipathy to Washington. But the antipathy, dormant perhaps, was still there. Three years after the end of the war, Southerners walked out of the Democratic convention over the segregation issue – specifically, the Democratic plank calling for a federal Fair Employment Practices Commission, which would have imposed non-discriminatory federal mandates on southern employment.

The 1948 election found much of the Deep South voting for a third party, the States Righters. And for years thereafter the one party domination was systematically shattered by the division between Loyalists and States Righters. Although Harry Truman had won in 1948 without the South, the conventional wisdom persisted that the South was critical to either party's presidential chances.

The GOP knew that even if the Democrats seemed to have forgotten. Gradually the States Rights factional disputes were eclipsed by the reflowering of the Republican Party in Dixie, not the least reason being the Supreme Court desegregation decisions of the 1950s, the civil rights act of 1964, etc.

First Goldwater then Reagan showed that the Solid South was no longer a Democratic given. The Party of Lincoln has now been rehabilitated as respectable and viable. No clearer evidence is needed than that Fob James won his first gubernatorial election as a Democrat but his last as a Republican, defeating the son of the man who had, with George Wallace, been in the small band of Southern party loyalists who refused to walk out of the 1948 Democratic convention.

Last Nov. 8 has been called, not inappropriately, a revolution. In that one day, Americans from coast to coast rejected Washington in the mightiest outpouring of secessionist sentiment since 1861. Figuratively at least, some kind of rebel flag was flying over most of

the 50 state houses. This time, Fort Sumter was taking fire from all points of the compass.

The central dynamics of the Democratic Waterloo was provided, pollsters now agree, by "angry white men." The perceived favoritism of the Clinton Administration toward blacks, gays, women and other putative victims of discrimination was undoubtedly a major factor in this anger. But it wasn't simply a national renunciation of what is now called victimology – government of, by and for the aggrieved. Just exactly what it was is not yet clear, but it **was** a rebel yell against the perceived sins of omission and commission of a central government grown too imperial for the average taste.

For a time at least, Speaker Gingrich's contention that he has a mandate to dismantle Washington, brick by brick and program by program, was not being seriously challenged. Certainly such decentralization measures as the bar to unfunded mandates was long overdue. But already there are muted doubts being expressed as to the wisdom of slash & burn tactics to destroy federal command and control. R.W. Apple writes (Jan. 29) in *The New York Times*:

"Yet the truth is that for all of the talk of decentralization, neither the liberals nor the conservatives wholly trust the states, at least not all of them. Welfare reform is a perfect example. Conservatives are worried about giving all the responsibility to the states because they are afraid some won't reform at all. Liberals are worried that some states will reform the system out of existence.

"There are other problems, too. In unbridled competition between the states, for example, what would prevent some states from cutting services and taxes to the bone to lure businesses, forcing others to do likewise and creating a downward spiral?

"Which takes us back to colonial days. The Founding Fathers were a committee, after all, and they could never quite resolve the question of how much had to be mandated from the center and how much could safely, from the perspective of the commonweal, be left to the tender mercies of the federal states. A tough call then, a tough call now."

Most of us would agree that it would be utter folly to turn the military over to the states. But after a few such absolutes, agreements begin to shatter: If welfare and Medicaid, say, would benefit by a divestiture of federal control, why not the FCC, FAA, the federal highway system, and just about every regulatory agency in Washington?

Why not, in fact, Medicare? If the very thought horrifies you – as I believe it would most affected Americans – you have thereby drawn a line in the dust: not **that** much decentralization.

A closer examination of some of the other divestiture talk may reveal similar misgivings. So far the wild jubilation of the new revolutionaries has neutralized the doubters. There really hasn't been a debate thus far in the 104th Congress. But I suspect the debate will begin, and it would not surprise me if the opposition to the Gingrich demolition derby is led by thoughtful members of his own party.

After all, if the United States is the greatest country on earth, the central government can't be all bad. It must be doing quite a lot of things right. To argue this fact is not radical, in my book, but very, very conservative.

PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

Are You Ready for Demassification?

I have watched with considerable interest, at times awe, Newt Gingrich's inaugural efforts to downsize the federal government. I want to be behind him but I am frankly a bit bamboozled by some of his comments and terminology.

I have made an effort to master the language of his campaign and have even drawn up my own glossary of terms, with what I perceived to be their definitions. Here's a start:

De-fund – To let die on the vine for want of nourishment; a legislative ploy in lieu of repealing laws, appropriations, agencies, etc., that utilizes starvation as the form of execution.

Zero-fund – A synonym for **de-fund**; to pull the plug, to remove life support, etc.

Devolution – The antonym of **revolution**; the overall process by which prior revolutions – viz., New Deal, Fair Deal, Great Society – are reversed. Remnants of some of these programs would devolve on the states, which would run them but with far less money, in block-grant form. As interpreted by contemporary scholars, the ultimate goal of **devolution** is to eliminate Washington altogether. It sounds like anarchy, but I'll buy it.

Demassification – The act of completely transforming a program, concept, law, etc., now applying to the **masses** into one applying to individuals; redistributing authority of the state as individual empowerment. Or something like that.

The last one I am not at all sure about. I remember reading about one old controversy that may have involved *demassification*, although the word didn't exist then. Back in President Eisenhower's Administration, his Secretary of Health, Education and Welfare (or maybe just Health back then) was a society lady from Texas named Oveta Culp Hobby. Mrs. Hobby got all bent out of shape because of a proposal for the federal government to fund the distribution of the newly discovered polio vaccine. Being a high-minded Texas lady, she said that would infringe on states' rights.

Herblock, the irreverent *Washington Post* cartoonist, depicted what he interpreted to be Mrs. Hobby's substitute plan, one that would preserve state's rights and individual responsibility: The federal government would give each American a monkey and a do-it-yourself kit for producing the vaccine.

That would have been *demassification* as I understand its present usage.

Each of my definitions were inferred from the context in which I have seen these neologisms used. It is my impression that one or more of the terms were derived from the writings of the futurists Alvin and Heidi Toffler, frequent speakers at Gingrich seminars.

Mr Toffler's book of a few years ago, *The Third Wave*, is said to be Mr. Gingrich's Bible. Hence we hear him and his supporters in the House (already dubbed Newtoids) disparage anything smacking of the Second Wave and applaud those ideas they believe to be acceptable as Third Wave stuff. Here is a skeleton guide to Toffler:

The First Wave was the time when our ancestors got tired of being hunters & gatherers and instituted agriculture. That is, to spare themselves all that walking and scrounging in all kinds of weather, they planted what they wanted in a nearby field, then sat back and watched it grow. Naturally, this luxury resulted in increased waistlines, and it can probably be shown that the diet fads began about this time, to say nothing of ladies' fashions.

The Second Wave is the one you and I grew up in without knowing where we were – heavy industry,

ushered in by the Industrial Revolution, James Watt's steam engine, textile mills, Henry Ford's flivver, jukeboxes, slot machines, air conditioning systems, and all that. The Second Wave has disappeared into the sunset, Tofflerians and Newtoids say, which may come as something of a surprise to business publications such as *Fortune*, which are even now frantically chronicling the resurgence of this country's industrial might in issue after issue.

The Third Wave, the information age, where we are now. Newt admonishes us to get with the cyberspace program or die. Up to a point his message is the same general warning as Al Gore has been trumpeting *ad nauseum* for years in his advocacy of government investment in the "information superhighway." Newt says Gore's *infobahn* is pretty commonplace already while the Speaker is thinking of giving laptops to the poor so they can tap into the Third Wave and make tons of money.

It's not clear how. Anyway, Mr. Gingrich advises us to buy stocks in barbell companies and the like because the Third Wave will end work as we know it and everybody will need a lot more artificial exercise.

While he's opposed to using federal funds for just about everything, Newt makes an exception in the case of space stations, which he and other Tofflerians can't stop talking about. Now, here is a case for *good* socialism, they say: for one thing the handicapped could find employment in space easier on them physically because of weightless conditions. Newt is a little vague on precisely what would be the nature of their work in orbit, but we know it won't be building anything, since he has already notified us that industry of all kinds is passe', strictly Second Wave, like chicken pluckers in Arkansas.

At this writing, the Speaker has just postponed his original January date to reveal how he plans to save $200 billion or so from federal spending, money he plans to use to give us all a tax cut. No reason was given for the postponement but there have been reports that the new Congress is already beginning to align itself into little pockets of defenders of various special interests.

For instance, the Senate Majority Leader, Mr. Dole, has let it be known that he won't look kindly on any attempts to slash the agriculture subsidy, which originated in the Great Depression but now benefits mainly agribusiness millionaires. Some of the biggest of these giant companies have home offices in Mr. Dole's Kansas and he numbers them among those he is counting on to bankroll his presidential campaign.

Awhile back, when he was just a backbencher tossing spitballs at everybody, Mr. Gingrich referred to his fellow Republican, Mr. Dole, as "the tax collector for the welfare state." Any day now you may hear him call the Majority Leader "bag man for the First Wave." Newt has presidential plans too, they say, and doesn't cotton to Dole's sharing the limelight of the devolution.

So demassification may get pretty rough before the year is out. With the help of a few cryptographers, I am still trying to crack some of the new code words. When I get a better fix on what Newt is saying about his plans for Medicare, for example, I'll let you know.

I'm afraid it's in serious trouble, however, He has already said it is too costly because so much of it is Second Wave.



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Communication and Deafness:

An Example Provided By Heather

*by Dennis G. Pappas, M.D.**

Communication through spoken language is uniquely human. Communication is all around us. It directs our actions. It informs us of all events. It keeps us intellectually active. The most important aspects of everyday communication are listening, speaking, reading and writing. Children normally learn to talk by hearing other people talk. Listening and speaking skills are most effectively acquired during the first few years of life. Listening and speaking permit the development of symbolic language, which is essential for learning how to read and write. Reading and writing join listening and speaking as the cornerstones of further linguistic and cognitive development. A normally hearing child requires no conscious effort and no conscious thought to develop the spoken language tools necessary for communication by age three. Studies have shown that about half of all intellectual development occurs in the first year of life.[1]

Hearing loss present from birth and during the early years devastates communication because hearing-impaired children, not identified as such until age two or three years, have not only missed the years that are crucial for learning speech, but they have learned to respond visually to the world around and to make do without spoken language. The habits they have formed as a result of not hearing are often inimical to the development of auditory speech perception and natural speech production.[2]

The ability to hear may be the single most valuable asset we possess. Helen Keller, blinded and deafened from eighteen months of age stated, "The problems of deafness are deeper if not more complex than those of blindness. Deafness is a much worse misfortune...for it means the loss of the most vital stimulus, the sound of the voice, that brings language, sets thoughts astir, and keeps us in the intellectual company of man."[3]

Heather Whitestone was deafened at age eighteen months. During and after the Miss America Pageant, her most moving feat was to understand and answer questions clearly. Many people with her degree of hearing impairment cannot communicate that well. True, her voice had a slightly tense and nasal quality, but her diction was excellent and her speech highly intelligible. The majority of hearing people were surprised, many shocked, by the fact that Miss Whitestone, so deaf from such an early age, was so comfortable with her verbal skills and her ability to function independently, without sign language interpreters.

An increasing number of hearing-impaired individuals do speak as well as Heather. Others speak in a monotone and have poorly enunciated "deaf" speech, while some, with less severe hearing impairment than Heather, cannot speak intelligibly and have to communicate mainly through signs and writing. Why is there variance in the communication skills of the hearing-impaired? Most differences reflect the nature of the hearing-impairment, the type and quality of medical and educational management they received as children, the type of communication mode selected, and the age at which treatment was initiated. While parents are usually expected to select the type of treatment their children should receive, they are not always made aware of the range of services that are available and the implications of choosing one form of educational treatment over another. In an ideal world parental choice should be dictated by the child's potential and individual needs but, in reality, choice is restricted, in large part, by socio-political pressures.

Hearing-impaired persons and their advocates, like society in general, are torn by schisms and form subgroups. While no one method of teaching hearing-impaired children can possibly meet the individual needs of all of them, each subgroup, frequently without due consideration of the individual differences that exist among hearing-impaired children, seeks to promote educational programs that reflect its own preferred form of communication. The concepts underlying the various views as to what is best for all hearing-impaired children have emerged as hearing impaired persons and other minority groups have come to achieve political significance. Hearing-impaired people, in much the same way as other minority groups, seek to achieve their goals though promoting public awareness of their needs and special interests. Those who advocate sign language, the *Culturally Deaf*, have become a highly visible force proclaiming the pride, power, and culture of their particular group. Those who speak, like Heather Whitestone, may have much worse hearing than many who are culturally Deaf but they are, as a rule, a much less visible minority

*Pappas Ear Clinic, P.C., 2937 Seventh Avenue South, Birmingham, AL 35233

because people do not recognize hearing-impaired speakers as essentially different from themselves, particularly as speakers tend to integrate effectively into the mainstream of society. Hearing-impaired individuals such as Heather Whitestone see oral communication as the main tool for integrating with the hearing world. There is, therefore, less social isolation of members of this group.

Disputes about modes of communication:

American Sign Language (ASL) is the communication system used by the group of people who are culturally Deaf. (The capitalization here is deliberate and indicates membership of a sub-cultural group). Most individuals in this group are prelingually deaf (deaf either from birth or before the age when children normally learn to speak). This is not to say that they all have too little hearing for the acquisition of speech. Many have more residual hearing than those who have learned and prefer to use spoken language. ASL is concept-oriented and does not include certain parts of speech. If deemed important to full comprehension in a given communication aspects of English such as articles and verb tense may be added to ASL by fingerspelling. Vocalization and lip-reading are not part of ASL. Sign languages such as ASL are now accepted as true languages, and function not only as a communication system but as an emblem for the culturally Deaf who feel that deafness should be regarded as a difference rather than as a handicap. They do not seek to function as part of a "hearing world." As members of a minority group, most Deaf adults want their children to be part of the Deaf culture.

The opposite camp, the "oralists," advocate speech, reading, and writing, as essential for success in the hearing world. Typically, most hearing-impaired people have at least some residual hearing that can be utilized with powerful hearing aids. Total hearing loss is extremely rare. For a child with profound hearing loss such as Heather Whitestone, the patient's residual hearing must be maximized, preferably early in life; sound strategies for hearing aid use must be utilized, and early educational opportunities should be provided. Modern technology and medicine, including the provision of specialized hearing devices such as hearing aids and cochlear implants, have made access to sound feasible for virtually all children with hearing loss. Families assume the responsibility for teaching their child to speak. They provide direction and support, including in many instances, the cost of the school setting of their choice.

Disagreements in deaf education are hardly new. Arguments over deaf education began in the 18th Century. After our colonial beginnings, the colonial fathers felt the need for a method of educating the deaf. Edward Miner Gallaudet was sent to Europe for this purpose. He found the oralists too secretive to reveal their skills for teaching deaf children. Gallaudet then identified with a predominantly manual teaching method. Sign language was endorsed in this country through a system of state endowed schools, such as the Alabama Institute of the Deaf and Blind.

Disputes over deaf education in this country date from the Nineteenth Century. Alexander Graham Bell, by trade and education a teacher of the deaf, had a deaf mother and deaf wife, and in his time led the movement towards the oral methodology of speech and lip-reading and reading. This method, though primarily visual, was supplemented by tactile procedures, in which the "listener" felt the movements and vibrations produced by speech on the talker's face or chest and matched them to the vibrations he or she produced in imitation. The movements of a speaker's mouth and the tactile-kinesthetic sensations produced by one's own speech are still regarded as a viable way to teach speech patterns that can be neither seen nor heard. A oral-tactile system was used by Helen Keller and has helped other deaf-blind persons to speak. Oral-tactile work has been improved as vibro-tactile and electrotactile aids have been introduced. Such devices are not a highly effective means of transmitting speech, but nevertheless can usefully enhance speech perception by children who have very limited residual hearing.

Current oral approaches, thanks to emerging technology, are now far more effective than they were even a few years ago. Most modern oral programs emphasize the use of hearing aids and cochlear implants along with lip-reading in order to develop speech communication skills. In recent years *auditory-verbal* programs have been initiated. They feature the perception of speech through hearing alone – an approach made possible through the development of increasingly high-fidelity hearing aids and cochlear implants. In auditory verbal therapy, lip-reading is suppressed for at least part of the time in order to focus attention on audition. Because this leads to children's improved awareness of their own voices, speech production is enhanced and in many cases reaches normal or near-normal standards of articulation.[4]

Cued speech is an oral system, invented by Cornett in the 1960s[5] that supplements speechreading by providing hand cues to identify visually confusable patterns. Vowels are identified by hand positions and consonants by finger configurations. Vocalization and prosody cannot be cued effectively. Children who depend exclusively on the system tend to make less than optimal use of residual hearing and rarely acquire natural sounding speech. All current manual approaches include fingerspelling. Fingerspelling is a system involving hand and finger configurations that represent each of the letters of the alphabet and permit the spelling of each word on the fingers of one hand. It is mainly used as a supplement to sign language or a sign system. Sign systems differ from ASL

in that they attempt to approximate the syntax of English rather than the very different word-ordering employed in ASL. Such sign systems include *Seeing Essential English. (SEE-1)* and *Signing Exact English (SEE-2)*. These systems were designed to permit spoken English and Sign to be presented simultaneously, a process known as *Total Communication*. Sign language purists object strongly to the process and believe that it would be better to teach using ASL and to treat the written forms of English as a second language.[6] Total Communication, however, continues to be the dominant system in most residential schools for the deaf. Although speech is included in Total Communication programs, less than half of the children in such programs ever learn to speak intelligibly.[7]

One of the factors that must be considered in selecting either an oral or a sign-language based method is the long-term cost effectiveness of the two basic systems. The ultimate cost/benefit analysis in relation to both the individual and society-at-large greatly favors orally educated individuals. While sign-language programs can be perhaps slightly easier and less costly to implement in the early years, modern forms of oral education can, as Heather has shown, better fit hearing-impaired individuals for a wider range of life-long personal, social and occupational participation as independent and contributing members of mainstream society.

Heather Whitestone's example and modern oral programs.

Heather Whitestone was identified with hearing loss at age eighteen months. She heard and developed speech and language up until that time. Having hearing for eighteen months gave her a distinct advantage in her later development, in that her brain had already developed pathways to the language centers. Typically, this development ceases and may even deteriorate unless oral instruction is quickly provided following the onset of hearing impairment. If therapy is not quickly provided, the words and sentences typical of hearing children of that age would soon disappear.[8]

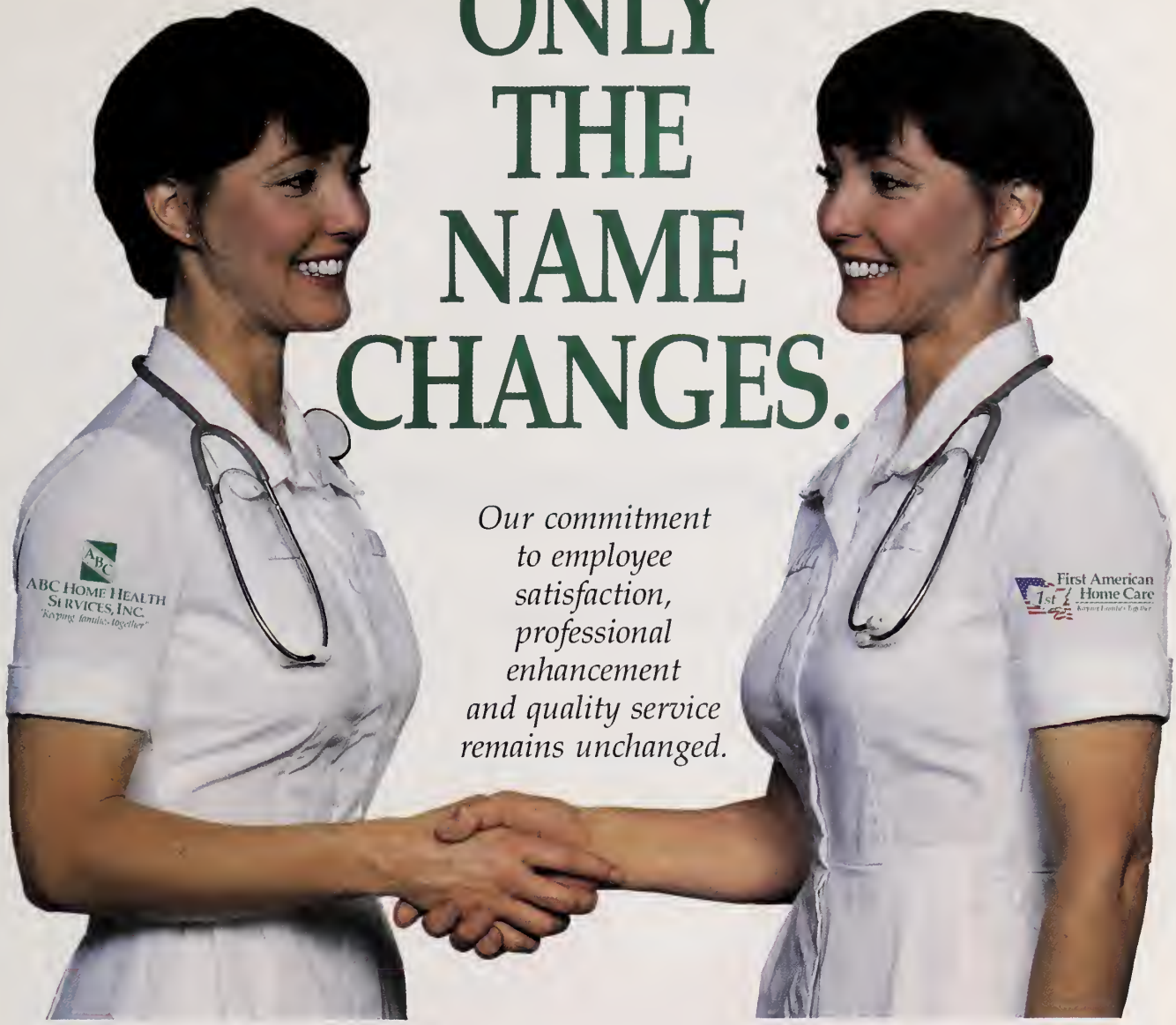
Miss Whitestone's hearing thresholds have been reported as severe to profound in one ear and total in the other. In her case, one hearing aid was applied to the ear with residual hearing. In a case such as Heather's, the audiologist would utilize a power aid to send as much sound into the now faulty auditory system which would convey this sound to the hearing-communication system of the brain. Regardless of the power of the hearing aid, it would not provide enough amplification to allow normal hearing. Therefore, at best, Heather Whitestone would have received a partial representation of the physical elements of sound of the human voice. At this point in the identification of hearing impairment, parents receive counseling to understand the meaning, impact, and importance of their child's hearing loss and ways to deal with it. Within one year of therapy children like Heather Whitestone, by utilizing the physical properties of sound (duration, frequency and intensity differences) even in a somewhat degraded form, can come to understand and say words like "ball" in simple sentences if they are repeated often enough in situations that give them meaning .

Parents in early guidance programs are counseled on optimal ways to encourage communication, particularly how to talk abundantly and effectively to their children about objects, people and the ongoing events and activities in which they are engaged. Teachers of the hearing-impaired and/or speech and hearing clinicians usually see the family in their own home or in a demonstration home (parent-infant center) and teach the parents how to use daily activities to help their child learn to listen. The child is repeatedly exposed to words and the actions which the words describe: getting a glass of juice, getting dressed, helping mother cook, and countless other activities that occur frequently in the home. The emphasis in such programs is to help the parents create an enriched supportive environment, not forcing, but always giving encouragement to their child, and working in ways that help her/him develop a positive self-concept.[9]

As the hearing-impaired child grows older, structured play activities such as one might encounter in kindergarten are implemented by a speech/language specialist. These sessions complement the continuing language work done by the parents in the home. In the case of Heather Whitestone, six years of language development had to be accomplished in 4½ years to prepare her to be mainstreamed into the first grade. Miss Whitestone's mother, in the mid 1970s, may have met opposition from the school system when she enrolled her daughter in the first grade. Currently, schools are mandated to provide special education and various support services for hearing-impaired children. The goals of mainstreaming are to permit peer-group interaction and promote the fullest development of a hearing-impaired child's potential.

The role of parents in developing a hearing-impaired child's spoken language as part of that child's whole and healthy personality is not an easy one. It is filled with apprehension, reservations, and fears about their child's success and future. Regular meetings allow parents to discuss their frustrations and experiences with the various professionals in the parent-infant program and with other parents. In spite of the every day frustrations met by the parents of the hearing-impaired children most who enroll their children in auditory-verbal programs and up-to-date oral programs end up finding and feeling that they have accomplished something of enormous value to their children's lives. Heather Whitestone certainly accomplished much more than winning the Miss America

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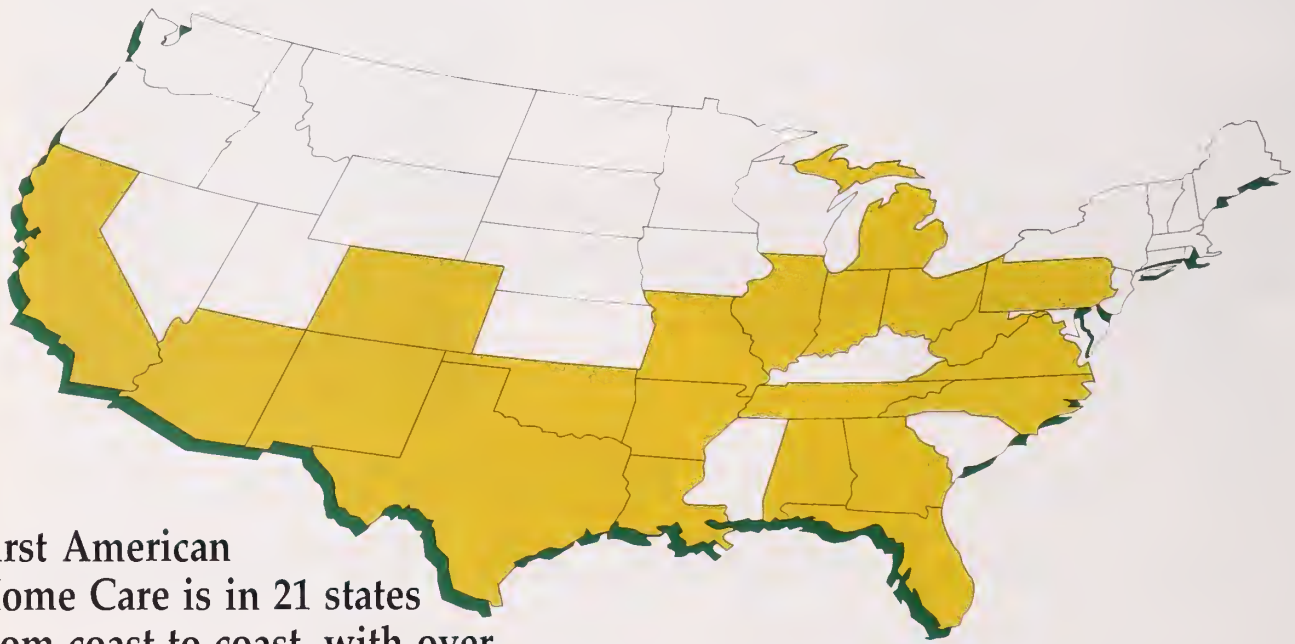
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Pageant – as a hearing impaired individual, she learned spoken language and social skills that made it easy for her to initiate communication and to respond verbally and appropriately in most situations.

The Role Of The Physician

The crucial importance of early identification of a hearing loss, early amplification with binaural aids, and the early onset of training and auditory-verbal therapy need to be emphasized. Success in achieving speech communication is, to a large degree, dependent on the early initiation of these diagnostic and remedial procedures. Linguistic delay and poor speech development among hearing-impaired children are too often due to delay in initiating a parent-infant program, inadequate attention to ensuring speech perception through the use of appropriate hearing aids, and meager language exposure. When a hearing loss is diagnosed late, the linguistic delay will be more severe; therefore, the physician should be well aware of his or her role in identifying hearing loss, determining its cause and ensuring that remedial measures are implemented without procrastination.

There are several factors which may influence the educational success of a hearing-impaired student. These factors include the individual's intelligence; the intelligence, communication modes and the participation of the parents; socio-economic factors; environmental interactions; psycho-neurological and psychosocial disabilities; the quality of the therapeutic program, and the amount of residual hearing and whether or not it is progressive in nature. It is precisely because so many variables are actively present and important in the treatment of hearing-impaired children that significant research in the field of their education has been, for the most part, nonproductive.

The primary and continuing role of any physician treating a hearing-impaired child is aggressive otological management, which includes determining the cause of the hearing loss and the provision of treatment for negative middle ear pressure, auto-immune inner ear disease, perilabyrinthine fistula, and so forth. The role of the physician in the habilitation of a child with hearing loss is not to determine if the child shall learn to speak or to sign, but to assist the parents in selecting the appropriate type of program for their child. Most physicians know very little about the philosophical differences in approaches to educating the hearing impaired discussed briefly above, but no-one is in a better position than physicians to ensure that parents receive appropriate advice on available services and are put in touch with the variety of resource personnel who, together with themselves, can provide an unbiased picture of the range of medical and educational treatments possible. Most parents of hearing impaired children are themselves normally hearing and upon finding they have a hearing impaired child have to learn about the facts and implications of hearing loss from scratch. Similarly, few deaf adults appreciate the opportunities that are now open for hearing impaired children to acquire spoken language skills, nor are they aware of the technological improvements affecting the quality of oral programs, for deafness does not make a person an expert on hearing impairment any more than ability to breathe allows one to appreciate the subtleties of pulmonary medicine. The physician must have the requisite knowledge to assist parents in reaching an unbiased, well considered plan for their child's educational treatment. In order to help them select the appropriate type of program for their child, parents must be aware of the various programs offered in the local area. The concept here is of the physician as a team leader in the management of the child as a whole person having access through other medical specialists, audiologist, speech-language pathologists and special educators. Access to this team will allow the parents to receive necessary information that will allow them to be well informed in the management of their child's hearing impairment.

Acknowledgements

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A Most Famous Doctor

Jack L. Zaremba, M.D.
Dorothy L. Miller, L.C.S.W.



Robert Davis Reynolds, Confederate Army, age 16.

"...the most famous doctor in all of this part of the state..."[1] That's what Dr. R. D. Reynolds was called in a 1904 edition of *The Ozark Tribune*. How did he earn such respect and recognition?

It could have been his expertise as a physician who had been in practice for over thirty years; or his reputation as a devoted family man with a wife and nine children —a man who regularly entertained large numbers of friends and family in his home; or it could have been his success as an astute business man, land owner, and bank director. Probably it was all of these—and the fact that he was totally blind.

Robert Davis Reynolds was born March 3, 1845 near Opelika, Alabama. He was the son of a physician, Dr. John Reynolds. As far as we know, his sight was normal during his childhood. He grew up on a farm, enjoying the fresh air and peacefulness of rural life.

That peace was shattered by the beginning of the Civil War. At the age of 16, he enlisted in the Confederate Army. He spent the next four years with Company K, 6th Alabama Cavalry under the command of General Abercrombie.

It is reported that Dr. Reynolds had "disturbed vision" at the end of the war. The cause of his vision loss is not known. His sight continued to worsen and he became totally blind in his twenties, while attending the University of Alabama Medical College in Mobile. Officials at the school put pressure on him to drop out. After all, they reasoned, a blind man could not possibly be a physician.

The school was unsuccessful in convincing Dr. Reynolds to leave. Instead, he hired a companion and reader and completed his medical education.

Dr. Reynolds married his wife, Mary Frances, and they had nine children; three daughters and six sons. He practiced medicine in rural Alabama for thirty five years.



Robert Davis Reynolds, M.D., practiced medicine for 35 years in spite of his vision loss.

"Each son in turn became his guide and companion during his trips to the country and to his office, and served as his eyes in the description of color of the patient's skin and eyes, taking the patient's temperature and such other details necessitating the use of eye sight."[2]

Around 1910, Dr. Reynolds retired due to failing health. On Monday, January 11, 1915, he was in town taking care of some business. That night he went to bed early complaining that he felt a little tired. He died quietly around two o'clock Tuesday morning, probably of a stroke. His obituary in *The Ozark Tribune* praises his life and accomplishments.[3]

Was Dr. Reynolds an extraordinary human being? Perhaps. Or maybe he was an ordinary man who, because of his blindness, was forced to deal with extraordinary challenges. He certainly made courageous choices—to live life to the fullest when it would have been easier to give in to limitation. He refused to allow vision loss to interfere with what he wanted to accomplish in life.

As his granddaughter put it in a recent letter, "....here was a blind man who was a successful doctor, successful in business, and in control of his life and family...he did not take advantage of his infirmity...he was not a person to be taken advantage of...blindness forged the steel of his character."[4]

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Recognizing Dr. Reynolds

Dr. R. D. Reynolds was recently recognized by the Southeastern Blind Rehabilitation Center, VA Medical Center, Birmingham, Alabama, for his determination to live life on his own terms in spite of vision loss.

The Southeastern Blind Rehabilitation Center serves veterans of all ages who are legally or totally blind. The visually impaired are taught skills to continue to lead useful, rewarding lives. Information about this program can be obtained by contacting the nearest VA Medical Center.



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Should Condoms Be

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Should we distribute condoms in schools? Some studies claim that condoms fail to prevent pregnancy transmission, estimates for failure rate range from0-31%. Neither does the literature agree about the doms offer good protection, others that a condom provides only a false sense of security. With that pre

Yes

by Leslie M. Kantor

By the age of 19, 82% of adolescents in the U.S. have had intercourse. The interval between the onset of puberty and the average age of first marriage has increased dramatically so that young people today begin having intercourse an average of eight years prior to marriage. Thus, although abstinence is the only 100% effective way to avoid pregnancy and STDs, parents, schools and communities must address the needs of the majority of adolescents for pregnancy and STD prevention. Condom availability programs are a new, important component of a comprehensive set of strategies designed to reduce teenage pregnancy and STDs. Condom availability programs make condoms available through school based clinics, by training select teachers to provide condoms at designated times or by placing condoms in vending machines.

Condom availability programs make condoms available through school-based clinics, by training select teachers to provide condoms at designated times, or by placing condoms in vending machines.

Condoms are usually given out free along with education about their proper use. Condom availability programs are widely favored; 65% of adults think schools should make condoms available to high schools students. Among sexually active teens, 80% believe condoms should be distributed in schools.

Condoms provide excellent protection against pregnancy and STDs including HIV. Numerous studies confirm this fact. The failure rate for the first year of use among perfect users is 3%. The first year failure rate among typical users averages about 12% and includes pregnancies resulting from errors in condom use. Among teens aged 15-19, the lowest condom failure rate is 11.4% while the highest failure rate is 19.3%. The highest failure rates for condom use are not found among teens, though; the highest failure rates are actually found among those users between the ages of 20 and 24. Condom effectiveness in preventing sexually transmitted diseases including HIV also appears to depend largely on the user. In a recent study of couples in which one partner is infected with HIV and the other is not (sero-discordant), among couples who used condoms every time they had intercourse, none of the seronegative partners became infected. However, among the couples who used condoms inconsistently, the rate of sero-conversion was 4.8 per 100 person-years. Condoms provide a barrier against hepatitis B virus, chlamydia trachomatis, gonorrhea, herpes simplex, genital ulcers and pelvic inflammatory disease.

Despite the fact that condoms are extremely effective, many studies show that significant numbers of sexually active teens fail to use condoms every time they have intercourse. One of the reasons for this is young people's lack of access to condoms at the time they engage in sexual behavior. Fifty-nine percent of teens who report that they sometimes do not use contracep-

Distributed In Schools?

21% of the time in the then population; others cite a failure rate in this population of 37%. For HIV dom's ability to prevent the transmission of sexually transmitted diseases. Some source saying con- consider the following arguments for and against condom distribution in schools.

by Charmaine Crouse Yoest

No

How safe is "safe"? Or "safer"? In any discussion of condom distribution in schools, this fundamental question must be keep clearly in focus. The bottom-line is that condoms are not effective in preventing pregnancy or the transmission of HIV. Presenting condoms to immature teenagers – particularly in a school setting – as safe, or "safer," is irresponsible public policy.

As a contraceptive, condoms have a very high failure rate. Planned Parenthood's research shows that condoms have a failure rate of 15.7% at preventing pregnancy over the course of a year. This is a standardized rate; for specific age and demographic groups, the rates soar to 36 and 44%.

Despite this unpromising performance, Planned Parenthood, SIECUS and others remain vocal advocates of distributing condoms in schools. They argue that more education would cut down on the user failure factor that contributes to these fluctuating failure rates.

This isn't just a debate about pregnancy and HIV prevention. It's about teaching teens to be healthy in all areas of their lives.

Would it? Research from the Alan Guttmacher Institute, an organization with close ties to Planned Parenthood, found that of women ages 14-44, women 20-24 had the highest failure rates. Surprisingly, women 15-19 and women 25-34 had very similar failure rates. The women in each age range were grouped into "high" and "low" rankings, reflecting the low and high rates of pregnancy among groups of women who have higher rates of user-failure – *only among women over 35 were all of the women in an age range able to achieve failure rates of less than 19%.* Even this last group of women – presumably more mature, in more stable relationships, better educated, and with overall lower fertility rates – report failure rates as high as 5%.

This gives us a rough idea of how well "more education" might work: Age, which generally correlates with more education and greater maturity, does make a difference. But not enough. When we switch to evaluating condoms for HIV prevention, the stakes are a lot higher: Failure is no longer measured by unwanted pregnancies. Failure is measured by death.

Nevertheless, despite its poor showing as a contraceptive, the condom has been reincarnated as a disease-preventing device. We now see dancing condoms in federally-funded television commercials, and hear from the Centers for Disease Control and Prevention and the Surgeon General that using a condom is the way to prevent the spread of HIV. This is simply not true. It is, in fact, a dangerous lie.

In a study published in *Social Science & Medicine*, Dr. Susan Weller, Associate Professor of Preventive Medicine and Community Health at the University of Texas, Medical Branch at Galveston, found that condoms had higher rates of failure in preventing HIV transmission than in preventing pregnancy. a Since some contraceptive

tion cite "lack of contraceptive availability at the time" as the reason. Clearly, one of the goals of condom availability programs is to ensure that young people who need condoms will have them when they do have intercourse. Other important objectives of these programs include the opportunity to provide education and counseling to sexually active teens. Many teens also report that embarrassment and the cost of obtaining condoms are prohibitive. Condom availability programs that allow students to obtain condoms in an anonymous or confidential manner and provide them free of charge help to overcome these obstacles.

Guidelines for whether to begin a condom availability program must take into account the median age of first intercourse in a given area, overall access to condoms and other contraceptive measures, as well as the political climate of the community. Many well thought out programs with adequate public health justification have been derailed because valuable community input and support was not sought prior to implementation. Currently, only 8% of junior and senior high school students live in districts in which condom availability programs have been approved. Because these programs are not widespread and are relatively new, most of the available data on their effectiveness is based on school-based clinics that distribute condoms or from information gleaned from project directors rather than from the scientific literature. These reports show that the number of condoms obtained varies widely but that young people are most likely to obtain condoms through those programs that give support and education such as through teachers' or nurses' offices. One study also found that in three schools, an additional 6-10% of students would have had sexual intercourse without contraception if the school had not provided contraception.

Perhaps one of the main reasons condom availability programs have not been widely implemented is that opponents of these programs have deliberately distorted data about condom effectiveness and sexuality education in an effort to bolster their argument that abstinence until marriage should be the only prevention information given in schools. Opponents who suggest: condoms have 5 micron holes in them (a bit of "information" taken from a letter to the editor which discussed latex gloves); (2) that sexuality education courses lead to increased frequency or earlier onset of intercourse (a World Health Organization meta-evaluation that reviewed thirty-five existing studies on sexuality education found that these programs both help students to postpone intercourse and to use contraception when they do have intercourse); and (3) that embrace the idea that abstinence-only programs that omit critical health information will help decrease unwanted pregnancy and STDs (despite the fact that no study on these programs has found them to be effective in changing students' behavior) are distorting the available data in service to a political agenda. Sexuality education and condom availability programs must be rigorously evaluated and modified to give young people the cognitive, effective and behavioral skills they need to maintain sexual health. Current studies on the effectiveness of sexuality education prove that those programs that are taught by trained teachers, focus on teaching young people the interpersonal skills they need to negotiate responsible sexual behavior and include information on both contraception and abstinence are the most effective.

However, condom availability programs are extremely new and tend to be small, so arguments about their effectiveness must be postponed until researchers have a few more years of data to analyze.

Educators must not promise that any one intervention alone will be enough to significantly impact the teen pregnancy or STD epidemics. These problems are the complex result of economic, environmental and psychological factors. Thus, condom availability alone will be a critical component of comprehensive health care in some communities. However, these programs alone are not sufficient. Condom availability programs must exist in the context of an overall health education program that includes sexuality education and begins in kindergarten with basic concepts that are expanded and broadened throughout the school years. A comprehensive approach must be coupled with efforts by families and communities to provide support and opportunity to young people. When communities and schools put together all of what is known to be helpful and effective, they have given children and adolescents the best possible chance to remain healthy and to go on to lead healthy lives. If politics and discomfort are allowed to get in the way, adults have failed to protect the nation's young people.

Leslie M. Kantor, M.P.H., is the SIECUS (Sexuality Information and Education Council of the U.S.) Director of Special Programs

Charmaine Crouse Yoest is a Bradley Fellow at the University of Virginia and a public policy consultant.

research indicates condoms are about 90% effective in preventing pregnancy, many people, even physicians, assume condoms prevent HIV transmission with the same degree of effectiveness," said Dr. Weller. "However, HIV transmission studies do not show that to be true. Effectiveness may be as low as 48% or as high as 82%."

Weller's conclusions are based on a meta-analysis of 11 studies of HIV transmission which involved a total of 593 partners of infected people. "Exposed condom users will be about a third as likely to become infected as exposed individuals practicing 'unprotected' sex," concluded Dr. Weller. "Thus, condom effectiveness or the risk reduction due to condom use can be estimated at 69%. Should our teenagers be told that a risk reduction method that fails 31% of the time is "safe"? Statistically, both teens and adults alike who are sexually active outside a monogamous marital relationship are protected far more by another factor: The relatively low risk that their partner is HlV-positive. Dr. Robert Redfield, one of our nation's top AIDS researchers at Walter Reed Army Medical Center, has stated publically that condoms "protect" only if both partners are HlV-negative. "Condoms may possibly be less dangerous," says Redfield, "but I would never call it 'safe sex' or even 'safer sex.' If one partner is HlV-positive, it is not safe. Period."

The underpinning of the universal condom use philosophy is the idea that everyone is at risk. Everyone. As a result, a negative view of sexuality is creeping– subtly and unacknowledged– into our public sex education. By distributing condoms to school children, and publically urging everyone to use a condom every time they have intercourse, we are teaching our children – as well as adults – to distrust the people with whom they are having sex. Why are we accepting, even promoting, the idea that one would sleep with someone one does not trust?

Most people do not behave that way. This is perhaps the most unrealistic element of the universal condom use policy: Most people (particularly teens) have convinced themselves that there is at least a minimum level, usually more, of trust involved before they decide to have sex with someone. The condom philosophy says just the opposite. Passing out condoms in schools is a fear-based approach to sexuality.

It communicates other negative messages to our teens. Is it possible that a teen can receive a condom from a teacher and then honestly think that teacher believes he or she has the strength of character to say, "no"? Do we want our teenagers to live up to this kind of expectation?

Imagine the scenario: A young man is trying to convince his date to have sex. She knows he has in his pocket a condom he received in school. Planned Parenthood's research shows that peer pressure and "thinking that everyone else is doing it" are the top two reasons teens have sex. What kind of added pressure is she feeling now? Even her school thinks everyone else is doing it.

These two teens go on to have sex, using that condom with fear, inexperience and fumbling. How realistic is it to think it was used correctly? Even if it was, how sad. The young girl probably didn't get HIV, but the condom didn't protect her from other sexually transmitted diseases, like chlamydia, that could impair her fertility later in life. And it certainly didn't protect her self-esteem.

The alternative scenario of two teens who use the condom flawlessly isn't a much prettier picture. That takes experience. Is that what we want for our teens? This isn't just a debate about pregnancy and HIV prevention. It's about teaching teens to be healthy in all areas of their lives. The research is quite clear: Teens who get involved in sexual activity have multiple partners, high rates of sexually transmitted diseases, lower grades and higher rates of suicide. Condoms don't provide protection for any of those consequences. Our teens deserve better advice. They deserve the truth about the power of abstinence.

Variations in Hospital Charges for Epidural Steroid Block

*J. Russell Eubanks, Jr., M.D.**

One-thousand five-hundred epidural steroid blocks (ESB) were randomly reviewed across the state of Alabama for one year. Costs were reflective of hospital site rather than technique used or medication administered.

Epidural steroid block is a widely used and accepted treatment for low back disability.[1] Because of the number of procedures performed and the costs of providing this care, there is increased interest in standardizing these costs. Interest has also been focused on indications for the ESB as well as repeat blocks and their effectiveness.[2,3]

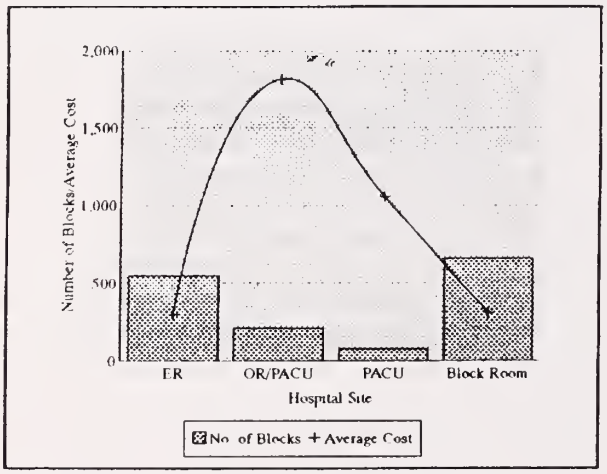


Figure 1

A review of 1500 randomly sampled ESB revealed a wide variation of hospital charges ranging from $224 to $2354. The median charge was $472 (figure 1). ESB's outside the hospital setting were also reviewed but not included in this study. Regional charges were similar but did reflect elements of cost shifting within the different hospitals.

There were twenty-four hospitals involved in the study as reflected in the demographic state map (figure 2). The largest hospital was over 600 beds and the smallest was 100. The predominant size was 300-400 beds.

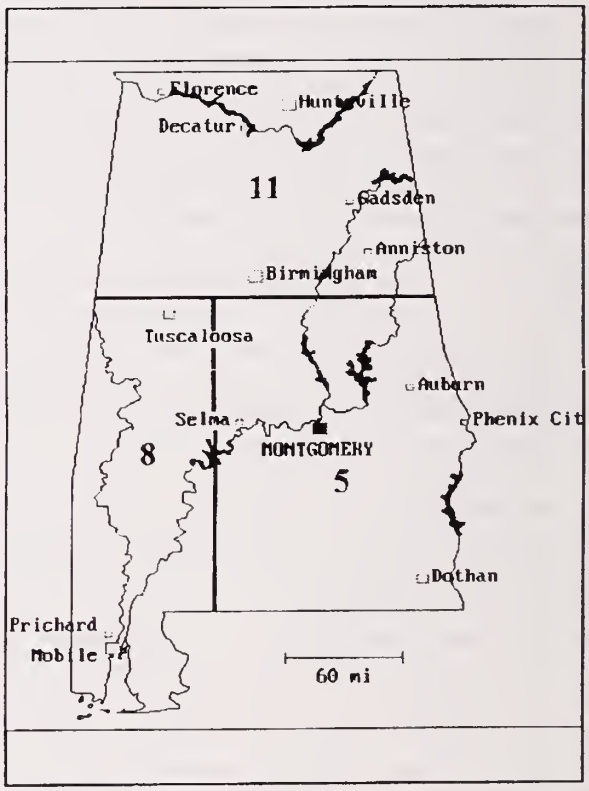


Figure 2

The utilization area most frequently employed was the emergency room and this area provided the least hospital charge (figure 3). The use of the operating room with post anesthetic care unit (PACU) follow-up incurred the largest charges. Other areas included block rooms and PACU for block and follow-up care. The charges for use of block rooms was slightly higher than the emergency room setting.

Medications injected generally included a steroid (methylprednisolone acetate-88%), a narcotic (fentanyl-89%) and varying concentrations of a local anesthetic (Bupivicaine-94%). Intravenous access was performed most frequently in the OR/PACU setting (100%) while the ER and the block room was the lowest (2.5%). PACU IV access occurred 95% of the time

Anesthesiologist, Thomas Hospital, Fairhope, Alabama. Associate Clinical Professor of Anesthesiology, University of South Alabama School of Medicine, Mobile, Alabama.

Hospital Site	No. of Blocks	Average Cost per Block
ER	549	$296
OR/PACU	212	$1814
PACU	78	$1060
Block Room	661	$307

with IV access and "butterflies," along with heparinloc catheters, were used for the remainder of the patients. Pre-ESB sedation was used almost exclusively in the OR/PACU setting. Medications included Midazolam, Propofol, Pentothal, fentanyl and meperidine. PACU stay for this group of patients was generally less than one hour (210/212 or 99%). IV access was used in the PACU 71 times (90%) with medication administered on 56 occasions (72%).

There were no charted indications for the variability in care. There was institutional and area consistency. Length of hospital stay was longest in the most complicated settings involving the largest number of medications administered. The average stay in the ER/block room was 55 minutes while the OR/PACU patient averaged 98 minutes.

The average cost for providing ESB in the ER or block room setting was $302 ($224-$502). The average cost in the OR/PACU was $1814 ($1372-$2354) and the PACU for block and recovery was $1060 ($844-$1386).

Information available for review did not allow for evaluation of outcomes nor was it intended as a review focus. In light of the medical environment today, outcomes and treatment effectiveness will be addressed.

With regard to the use of IV sedation prior to and even during an ESB, there seems to be a trend to increasing use. There were many more instances over the latter part of the 12-month period (March to June51%). This, however, may be a sampling error. Presenting these variations in care is not intended to be divisive but does point out a need for review and discussion of a popular medical procedure. If reimbursement is formulated as a procedural cost, some standardization may be necessary if hospitals are to remain fiscally viable.

Finally, outcome studies for ESB are available for review but generally do not include these variables.4 In my opinion, there should be some hospital charting method that will reflect patient outcome and effectiveness of treatment.

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Who's your No. 1 doctor?

With more doctors competing for the role of primary-care provider, the answer is tricky

U.S. News & World Report

San Diego obstetrician-gynecologist Donald Byrnes is not particularly well versed in ailments above the neck – nor did he plan to be. He certainly never dreamed he'd be giving up a Friday evening and Saturday morning a month for 10 months to relearn general medicine. But here he is, poring over a fat notebook, studying migraine symptoms in a stuffy conference room on a glorious Saturday.

Primary care, long the low-paid, poor cousin of specialty care, is hot. More insurance plans insist on a generalist's office as the first step in medical care – and often patients go no further. "The primary-care doctors aren't referring to us anymore," says Byrnes. So some specialist are swallowing their pride and catching up on development in general medical school. But is a weekend-trained gynecologist or other specialist – a person who has spent the years since medical school immersed in dealing with only one area of the body – competent to spot, diagnose and treat the wide range of common ailments that are a trained family practitioner's specialty? Are generalists, commonly accepted as internists and family practitioners with a wide breadth of experience, equipped to delve deeply into illnesses usually handled by specialists?

Those are hard questions that nonetheless must be asked of doctors who hold themselves out as primary-care providers. Patients who get all their care from specialists should ask how their doctors keep up with changes outside their speciality. Patients whose chronic diseases are handled by generalists should be still more pointed. "If you're seeing a generalist for a condition for which specialists are often used, make certain you ask if the doctor is in contact with a specialist. Ask if he's up on the research in the area of your illness," says Carolyn Asbury, director of the Health and Human Services Program of the Pew Charitable Trust.

Leading the movement toward more primary care are those Americans—more than 40% and climbing—who are enrolled in health maintenance organizations or other managed-care plans. It was the growing enrollment of Southern Californians in such plans that led Byrnes, after 29 years as an OB-GYN, to brush up on general medicine. He has always provided such care to his women patients but wasn't overly concerned with problems of the head, heart or gut. "We referred them to someone else," he says.

"This is an intrustion." With health plans increasingly frowning on referrals to specialists, however, Byrnes and 19 of his fellow OB-GYNs have gone back to school. All practice independently at Sharp Medical Center, a San Diego facility that also has its own managed-care plan, Sharp HealthCare. These doctors care for women enrolled in the plan, see private patients and contract with other managed-care plans. After their retraining, they will be designated as primary-care providers by Sharp HealthCare, with no guarantee that other plans will honor their primary-care training.

Some of the OB-GYNs see retraining as a welcome change. Others yawn or fume. "I'm a specialist. I'm busy. This is an intrusion," snaps one doctor. But 82% of San Diego's physicians are specialists, against 65% nationally, and the imbalance is too great. "If you don't do primary care in this town, it's career ending," says Byrnes.

It's not that OB-GYNs provide no primary care. A 1993 Gallup Poll shows that 54% of women ages 18 to 65 think of an OB-GYN as their primary physician. But most primary care comes from internists, specialists in organ diseases, and family practitioners, specialists in general medicine. Pediatricians, of course, provide primary care for children.

Proof of competence? Besides the San Diego program, more than 20 other retraining efforts around the country for OB-GYNs or subspecialists in internal medicine are in the works. Sarena Seifer, health policy fellow with the Center for the Health policy fellow with the Center for the Health Professions at the University of California at San Francisco, has examined them all and concluded that while some programs are sound, there is no consistent test of competency following retraining.

Subspecialist like nephrologists, rheumatologists and cardiologists, citing their three-year residency in general internal medicine, are jumping on the primary-care bandwagon. Even nurse practitioners and physician assistants are setting up primary-care practices.

But the standards primary-care providers should

meet are still being worked out. The Institute of Medicine, which is halfway through a two-year study on the future of primary care, defined such care in an interim report last September: A primary provider is a patient's first and regular contact with the health care system. And while the care is not always definitive – a consultation or referral might be called for – primary-care providers know who else patients are seeing for care, the tests they are receiving and the drugs they are taking.

Picking up nuances. By those standards, J. Brian Copley, a nephrologist at Ochsner Clinic in New Orleans, can say his kidney patients can look to him for primary care. They include Bertha Koenig, who remembers well a general practitioner she saw in 1932 for a pain in her side. He diagnosed a kidney stone and said it would dissolve on its own. In 1960, a specialist removed her kidney, which had been destroyed by the recalcitrant stone. Four years ago, when her remaining kidney began to deteriorate, she wanted the expertise of Copley – whom she had been seeing for her kidney problems – available during all her exams. "He took over everything – the high blood pressure, the general checkups," says Koenig, now 88 and doing fine.

Nephrologists and endocrinologist have long been the main resource for diabetics, rheumatologists for arthritics and cardiologists for those with heart disease. A generalist might overlook nuances of change that a specialist would catch, says Howard Price, a cardiologist at Ochsner. "I've seen patients where a generalist has missed subtle signs of congestive heart failure," he says.

While nephrologist Copley enjoys providing primary care, not all specialists do. Price, for example, has a full load of cardiac patients and doesn't want to have to absorb an avalanche of new information. Patients should ask if a specialist is willing to take over their primary care, and with what limitations. Copley says he's comfortable with everything but OB-GYN. "I would have to receive training in gynecology. I refer patients out for pelvic exams," he says.

Many rural Americans, like the 2,020 residents of Enterprise, Ore., don't understand the fuss. In places like Enterprise, most medical care comes from a broadly trained doctor or two; referral to a specialist is rare. Tucked in the Cascade Range in the northeast corner of the state, Enterprise is a six-hour drive from Portland's academic medical center, an hour and a half west over winding mountain roads to specialists in La Grande and three hours north through majestic blue-green pine forests to the nearest cardiologist in Walla Walla, Wash. Most of the time, all the doctoring in Enterprise comes from one family practitioner and one internist.

For the Stangel family, the system has worked for three generations. When Bud Stangel, 70, needed prostate surgery, Lowell Euhus, the Enterprise family practitioner, assisted in the operation at the 33-bed Wallowa Memorial Hospital. When Margaret Stangel, 68, though she had the flu but Euhus wasn't sure, he sent her to a urologist in La Grande, who found a urinary problem. The Stangels' three boys and one girl stayed on in Enterprise after college, and all 12 Stangel grandchildren were delivered by Euhus, seven by caesarean section.

Cows and chemo. Euhus keeps current largely through daily phone calls with specialists. One day recently, he consulted with a facial plastic surgeon about a man kicked in the head by a cow, with a cardiologist about a woman injured in a car accident and with a neurologist about a man who had fallen off a horse and hit his head. Earlier, he spoke with an oncologist at the Fred Hutchinson Cancer Center in Seattle to work out chemotherapy for an 11-year-old girl with leukemia so she could stay home with her family.

But new managed-care rules, even in remote Enterprise, have put some of Euhus's network of specialist consultants out of reach of Medicaid patients, who can get care only through Medicaid's network of doctors and hospitals. That rules out the cardiologist in Walla Walla, and Euhus has had to send some Medicaid heart patients to Portland, more than twice as far away. Additional limitations from private insurance plans are inevitable, so he and three of the other four primary-care doctors in the county have joined a La Grande IPA, or independent practice association. Together, generalists and specialist hope to be in a better position to negotiate contracts while continuing to be able to refer to each other.

Such business arrangements are a trend that can squeeze consumers. They may find themselves in a new plan that lets them keep a favorite doctor for primary care but reduces that doctor's referral pool. Families may have to set priorities when changing plans, gathering as many desired specialists as possible under one plan who are still within the network of a favored primary provider.

Many rural Americans have gotten used to getting basic care from nurse practitioners or physician assistants, who are becoming fixtures in urban and suburban clinics and doctors' offices as well. Christine Dufrane, 30, chose Kaiser Permanente, the country's first and largest HMO, because of the nurse practitioners available at the nearby clinic in Towson, a Baltimore suburb. "I think nurse practitioners have a caring rapport," says Dufrane. Sure enough, as 6-month-old Emily Dufrane sits up without toppling, nurse practitioner Donna Dearborn reacts as if the baby is a budding genius. In more practical matters, Dearborn offers folksy wisdom. "Use key words like 'hot,' 'dirty,' 'hurt.' Don't use 'no.' 'No' means so many things that by the time they're 2, it has no meaning," she says.

Dufrane's belief about rapport is well founded. A

1993 analysis of 200 studies of nurse practitioners by the American Nurses Association found that they spent an average of 25 minutes with each patient, compared with 17 minutes for doctors. Other studies show they provided more health education and that the routine care furnished by nurse practitioners was as good as that furnished by doctors.

Technically, both nurse practitioners (registered nurses with three more years of training) and physician assistants (who have two years of special medical-school training) are supervised by doctors. In practice, they manage a host of routine ills, from diagnosing strep throat to monitoring hypertension.

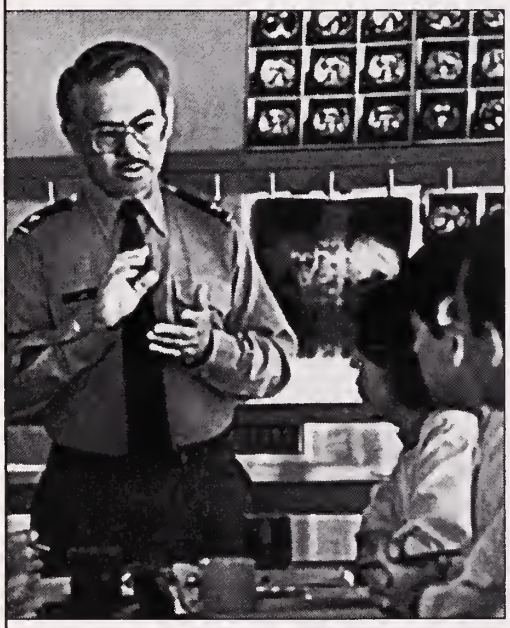
Choosing the M.D. Nonetheless, their condensed medical education is bound to make some people uneasy. Kaiser Permanente's Towson clinic patients can take their children to Judith DeJarnette, pediatrician at the clinic. On DeJarnette's days off, however, all sick children see Dearborn as their fist contact.

Kaiser's policy is for patients who choose a nurse practitioner or physician assistant to see the supervising physician from time to time – every third visit in the case of obstetrics, for example. That's because it is the doctor who will deliver the baby or outside obstetricians who will deal with more difficult problems that come up unexpectedly.

For the most part, though, physician assistants and nurse practitioners do as well as doctors. The Office of Technology Assessment analyzed both professions in 1986 and found that routine care given by nurse practitioners and physician assistants is as good as that provided by doctors. More recent research reaches the same conclusion.

If nonphysicians can handle a rash, cough or earache, so can a growing variety of doctors. Part of Medicine's inevitable future, it seems, is a scene in which a woman asks her OB-GYN about her migraines.

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Lessons From AIDS

*Ernest S. Campbell, M.D., F.A.C.S.**

Reflecting back on our experiences with AIDS during the past 12 years, there are many lessons to be learned. In some respects the experience has been analogous to the spin-off from the U.S. space effort, mobilizing dormant federal agencies to encourage advances in clinical, therapeutic, social and viral research which would not have occurred otherwise. In other respects it has been a public health disaster, allowing one of the world's most devastating epidemics to get out of hand.

Any chance to control AIDS when the first case was reported in 1981 was lost when our public health service was taken by surprise, having no idea what was causing the disease complex destroying the immune systems of otherwise healthy young men, thereby allowing opportunistic infections and cancers. When the virus causing the illness was identified two years later as a retrovirus, too late for basic public health control, the highly contagious, fatal illness had been allowed to proceed unchecked. Now a pandemic, it affects some 8-10 million adults, 1 million children and the World Health Organization estimates that it may reach 40 million people by the year 2000.

How could this have happened in an era with such a strong history of successful epidemiological control of major diseases? Some feel that we had the ability to contain this disease from the outset but failed to do so because of definitions of the disease applied by the CDC. Even after it was identified as a retrovirus and named "human immune virus," a patient had to have certain opportunistic infections before a diagnosis of AIDS could be made. It was not until 1992 that the CDC expanded it's definition of AIDS to include those people with a CD4 cell count below 200, dramatically increasing the number of people who could be treated for AIDS by about 40%.

Even after the cause of AIDS was determined no widespread control measures were instituted. These control measures have had a long history of success, stopping such diseases as yellow fever, small pox, cholera, tuberculosis, polio and controlling the sexually transmitted diseases, syphilis and gonorrhea. Using good public health measures, some of these illnesses were controlled even before their causes were known. Why were health agencies loathe to apply appropriate measures to stem an epidemic that can only be described as a 20th century plague?

A thoughtful person might feel that the underlying cause of this omission was complacency brought on by an era of antibiotics, vaccines and immune sera. Possibly thinking that this was just another ordinary virus, they might have felt that they could rely on our pharmaceutical industry for a "magic bullet"cure. On the other hand, quarantine was unthinkable, if not impossible, because of the population initially involved. Initially a disease of the gay community, accounting for over half of the AIDS cases in 1990, significant lobbying pressure from this extremely well organized and vocal group prevented adequate case control and contact followup. Institution of appropriate blood testing was not allowed in the schools and workplace because of the fear of discrimination.

Fear of discrimination resulting from a positive HIV test has until recently blocked testing of emergency room and other hospital patients. Without a written informed consent to do the testing, hospital administrators have been reluctant to do routine testing for the AIDS virus. Because of this lack, hospital personnel have been exposed to grave danger from having to operate upon and treat patients of unknown HIV status. The same has been true of donor testing of blood with untested, tainted blood causing many cases of AIDS in the early years of the epidemic. Tragic HIV infections have occurred in professional personnel because of this "politically correct" lack of information.

A whole new cottage industry has been developed in the process of dealing with this new disease. In the operating room, new techniques have been developed to protect the surgeon and other personnel. Impervious masks and shields, disposable gowns, and needle proof gloves have been developed. In unprecedented action, possibly responding to pressure from activist groups, the FDA has speeded up it's review process of approving drugs possibly effective against the HIV viral agent and infections brought on by a weakened immune system. Important drugs have been released which can delay the onset of AIDS in the HIV positive patient. Other "spin-off" drugs, have been developed which are effective against complicating infections associated with AIDS; cytomegalovirus, pneumocystis, Kaposi's sarcoma, major fungal infections, and severe anemia.

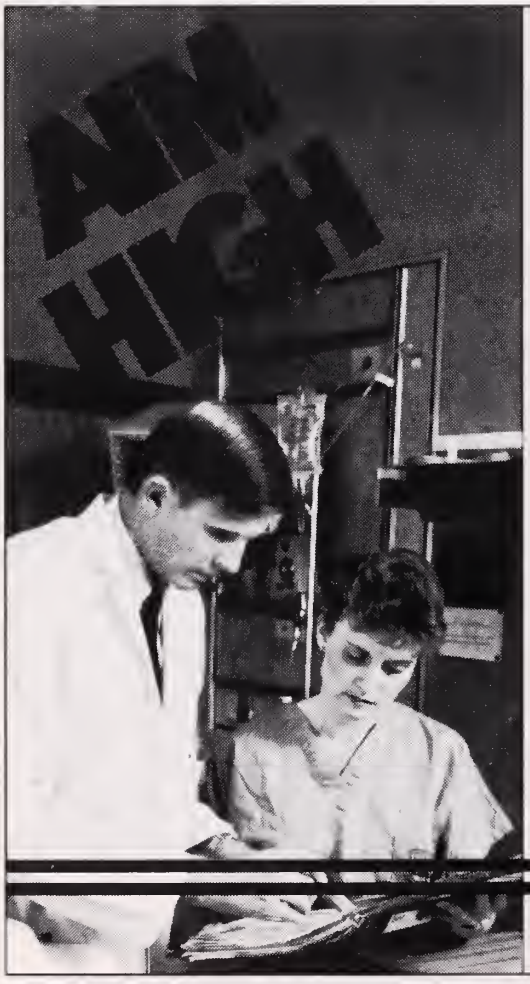
Recent efforts directed toward prevention of this mostly sex-transmitted disease have been admirable. Intensive educational programs have been directed toward the young and sexually active, flooding them

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with information about "safe sex," condom use and abstinence. Needle exchange programs have been successful to a degree in reducing the addicts exposure to HIV. Extensive lobbying by surgeons' and hospital groups has gradually relieved some of the restrictions on widespread HIV testing. However, because of the social and economic ramifications of a positive HIV test, little has been done in the area of broad-based testing of the populace.

Most researchers and clinicians feel that the best hope for control of the AIDS pandemic is a vaccine. Several animal studies with vaccines may show theoretical promise in humans. A preventive vaccine would be the ultimate goal, but a post-exposure shot might be helpful in boosting the immune response in the already infected individual. Factors blocking the development of a good vaccine are associated with the variability of the virus from one patient to another (similar to the common cold), and the lack of a good animal model for study, (the chimpanzee gets the HIV virus but doesn't get AIDS).

Until an effective treatment is found AIDS patients can only continue to derive benefit from treatment of associated infections and to enlist help from family, friends, counselors and support groups. Recently described "natural immunity" in multiply-infected West African prostitutes may be a clue as to a way to eventually stop the spread of the disease. If this doesn't happen, one has visions of the human race evolving through a process of "natural selection" from those of us who are either monogamous or asexual — hopefully the former, if our race is to continue as the dominant animal on this planet.



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MASA SPECIAL REPORT

Alabama Impaired Physicians Committee

The Physicians Recovery Network
Gerald L. Sumner, M.D., Medical Director, PRN
William M. Lightfoot, M.D., Chairman of the Board of Censors

The Medical Association of the State of Alabama (MASA) has for many years recognized the need to assist the sick physician. MASA, in a cooperative effort with the Alabama Board of Medical Examiners (BME) developed the Alabama Impaired Physicians Committee (AIPC) in 1988 to promote early identification of the physician who may be ill as a result of substance abuse, mental or emotional illness, including personality disorders and allegations of professional sexual misconduct. Placed under the auspices of MASA, the AIPC develops the policies and procedures for the impaired physicians program, known as the Physicians Recovery Network (PRN). The AIPC has directed the PRN as a full-time program since October 1, 1991. During the past three and one-half years PRN has been realizing its goal in assisting sick physicians to redirect their lives to be productive individuals in society. This report outlines the PRN program available to all physicians in Alabama.

Why was the AIPC established by MASA?

MASA recognizes that physicians troubled by chemical dependency or mental/emotional illness first experience personal, family, or other inter-personal distress prior to impairment in their medical practice. These physicians are described as impaired when such illness is immediately likely to impair or has impaired their ability to practice medicine with care and safety.

What is the legal standing of the AIPC?

Act 88-536 of the 1988 regular session of the Alabama legislature enabled the BME to contract with MASA for the creation of the AIPC. This legislation provides in some cases a therapeutic alternative to the disciplinary process. In other cases it allows therapeutic intervention and treatment concurrent with the disciplinary action. It recognizes that illness and recovery are mitigating factors in Board disciplinary procedures and offers incentive for early intervention and treatment. It also provides the licensee an opportunity to re-enter practice after completing treatment and progressing satisfactorily in recovery.

Is there a philosophy behind the PRN Program?

In establishing the PRN, MASA affirms that drug and alcohol dependence and mental/emotional illness are diseases which can cause physician impairment; that these diseases can be successfully treated in most cases; and that following successful treatment, physicians can continue or resume a successful and productive practice of medicine.

The PRN works with county medical societies, medical specialty societies, hospitals, medical schools, self-help groups, and other concerned organizations to achieve its basic purpose of intervention, rehabilitation and prevention. Hospitals, clinics, medical schools, and other institutions are encouraged to develop their own impaired physicians policies and programs with which the PRN can cooperate by accepting referrals. These referrals are considered confidential, and the process ensures that public record will be avoided and the tendency of litigation significantly reduced. More importantly, PRN recognizes that impaired physicians may feel more comfortable discussing personal illness or career concerns with a physician colleague.

How are impaired physicians brought to the attention of the PRN?

Physicians helped by PRN are identified by fellow physicians who care enough about them to help them recognize their illness. Referrals may also be made through a help line (334-261-2044), from friends, families, physician colleagues, hospital administrators, nurses, or others. Self-referrals are encouraged.

The BME may also refer physicians whom their investigations determine are suffering from an illness that may predispose to impairment in medical practice. The AIPC's assistance in achieving recovery can be instrumental in these circumstances in preserving the physician's medical license and assuring patient safety.

Physicians retired from practice, those working in Alabama but not licensed, residents, medical students, and physicians' assistants are all within the scope of the AIPC. ***It is imperative that physicians recog-***

nize that they will not be identified as reporting a fellow physician, but that their actions can be the key element in saving a life and a career.

How does the intervention process work after a physician is referred to the PRN?

Intervention is a process of personal contact with the physician believed to be troubled or impaired. Once it is determined that the physician is troubled, the physician is urged to become involved in evaluation and/or treatment. Intervention may be conducted by a local volunteer physician, coordinating with the medical director of PRN, members of the AIPC, and others as may be appropriate to the case. Some issues to be explored during intervention are:

a) Does the physician have an alcohol, drug, mental or emotional problem requiring evaluation?

b) Is the problem causing impairment in the individual's ability to practice medicine? If so, is there evidence of imminent danger to the public?

c) Is there a history of previous treatment?

d) Is the physician motivated to enter or resume treatment and to participate in the impaired physicians program?

e) What is the potential for involvement by family members in the rehabilitation process?

f) Is there imminent danger of suicide?

If the physician agrees to join the PRN, the medical director or his designee will formulate a recommended action plan based in part upon the recommendations of the treatment provider performing the evaluation and/or treatment. This may include further medical or psychiatric evaluation in order to clarify the diagnosis or to make better specific treatment recommendations. Direct referral to in-patient or out-patient treatment may be recommended.

Special medical examinations may be requested to determine the nature, presence, and extent of impairment. Results of the evaluation will be used to determine the level of program participation and to develop treatment and monitoring plans.

Will PRN recommend a specific treatment plan?

Although the PRN program does not engage in treatment per se, a recovery or rehabilitation plan will be prepared and updated for each program participant by the medical director or his designee in consultation with the reported physician, those treating him, his close associates, and others as appropriate.

Treatment may include in-patient or out-patient services for de-toxification, rehabilitation, psychiatric care, and/or attendance at self-help and peer support groups. Urine drug screens will be offered for documentation of continued recovery as may be needed for the BME, hospitals, other physician groups, and liability insurance companies. Changes in treatment must be approved by the medical director. Treatment providers will only be part of the treatment plan if they are willing to cooperate with the impaired physician's advocacy program. This means reporting continued attendance and participation in treatment.

Family participation in treatment is acknowledged as critical to the well-being of the family and other intimates, in addition to recovery of the physician in this program.

Will a physician's dependency problem be kept confidential?

Yes. Alabama law expressly exempts the AIPC from the requirements of reporting impaired physicians. PRN reports activities to the BME, but physician identities are never revealed except under the following circumstances:

1) If it is determined that the physician is presenting an imminent danger to the public;

2) If the physician is believed to be impaired and refuses to cooperate with the AIPC after sufficient committee efforts; and

3) If, during treatment, he does not follow the treatment plan and/or does not respond to treatment.

In addition, the confidentiality of records maintained by the PRN is protected by federal law and regulations.

How can I get more information on the PRN?

The PRN can be reached by contacting the Medical Association of the State of Alabama, 19 South Jackson Street, Montgomery, Alabama 36102-1900, telephone (334)263-6441, (334)261-2044, or 1-800-239-6272.

Mandatory Lead Screening In Madison County:

Is It Necessary?

Rachelle Cassity, M.D. *
Douglas Everett, M.D., M.P.H.

Public health programs often involve screening entire populations for pathology. Although many screening activities have proven medically beneficial, there are recognized detrimental effects of universal screening, including false positive identification, inappropriate therapeutic action, poor clinical correlation, high costs, and misprioritizing health care needs. These detrimental effects have recently been raised in connection with childhood cholesterol screening, as well as blood lead level screening[1,2,3,4,5].

Although some of the scientific studies on which the new lead screening standards are based have been questioned, it is not the purpose of this report to challenge the government mandate for universal lead screening. That argument was made more eloquently by the *Wall Street Journal* article of David Stipp in 1993[4]. As practitioners, we wished to investigate if our community would qualify as having no childhood lead problem and, therefore, be eligible for exemption from the federal requirement.

A detailed European analysis concluded that "it is still not possible to conclude with any certainty that lead at low levels is affecting the performances or behavior of children"[5]. In addition, some of the scientific studies on which the new lead screening recommendations are based have been challenged. There is no dispute that lead in the blood can serious health problems, rather, the dispute is just how little lead in the blood causes effects serious enough to demand medical intervention[6].

Over the years, the Centers for Disease Control and Prevention (CDC) accepted lead levels in the blood have constantly been lowered from 60 mcg/dL in the mid-1960s to 30 mcg/dL in 1978 to 25 mcg/dL in 1985 and is currently being lowered to 10 mcg/dL with intervention for individual children beginning at blood lead levels of 15 mcg/dL.

Despite the problems with public health screening programs, the federal government decreed in 1991 "that because almost all U.S. children are at higher risk for lead poisoning (although some children are at higher risk than others), our goal is that all children should be screened, unless it can be shown that the community in which these children live does not have a childhood lead poisoning problem"[7]. As a consequence, lead screening in our Medicaid population has been mandatory in Alabama since 1992 as part of the Early Periodic Screening, Detection, and Testing (EPSDT) Program. In this program each child under the age of six years is required to undergo an annual capillary stick for lead levels as a part of the EPSDT screen. If the lead level is 15 mcg/dL or higher, the results must be confirmed with a venous sample. Once the results of the venous sample are obtained, the child is placed in a class according to Table 1 from CDC's *Preventing Lead Poisoning in Young Children* October 1991 and treated appropriately[7].

Table 1 Class of child and recommended action according to blood lead measurement

Class	Blood Level Concentration (ug/dL)	Action
I	less than or equal to 9	Low risk for high-dose exposure rescreen as described in text High risk for high-dose exposure rescreen as described in text
IIA	10-14	Rescreen as described in text If many children in the community have blood lead levels less than or equal to 10, community interventions (primary prevention activities) should be considered by appropriate agencies (see chapter 9)
IIB	15-19	Rescreen as described in text Take a history to assess possible high-dose sources of lead Educate parents about diet, cleaning, etc Test for iron deficiency Consider environmental investigation and lead hazard abatement if levels persist
III	20-44*	Conduct a complete medical evaluation Identify and eliminate environmental lead sources
IV	45-69*	Begin medical treatment and environmental assessment and remediation within 48 hours
V	greater than or equal to 70*	Begin medical treatment and environmental assessment and remediation IMMEDIATELY

* Based on confirmatory blood lead level.

We reviewed the results of the first complete year of screening, 1993, in Madison County, Alabama to determine if universal screening in our population was worthwhile. In Madison County, 2,163 children were screened, four had blood lead levels greater than 14 mcg/dL, which is the reportable level in Alabama. One mother, who worked with ceramics, requested her child be screened. The child's lead level of 16 mcg/dL fell below the reportable 15 mcg/dL when the mother changed her work habits. Three lead levels between 20-27 mcg/dL were found during a lead abatement project in the Mason Court Public Housing area. Blood lead levels fell below the reportable 15 mcg/dL when the project was completed.

Schlenker performed a cost-benefit analysis on lead

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screening for levels above 24 mcg/dL[8]. He determined screening pays off in any community with a lead poisoning greater than 24 mcg/dL prevalence of 1 per 1,000. Since the three elevated lead levels related to the Mason Court lead abatement project were temporary, predictable, and required no medical intervention, universal lead screening was of no utility in those cases. The blood lead levels in these three cases were 20 mcg/dL, 25 mcg/dL, and 27 mcg/dL, meaning that only two met Schlenker's cut-off. The other case of the mother working with ceramics was identified by the mother's concern and not from universal screening. In any case, the level was well below Schlenker's criteria of 24 mcg/dL, so it would not have been included. Therefore, even if the Mason Court abatement cases were included, only two cases out of 2,163 screened would meet Schlenker's criteria. Thus, Madison County has less than 1 per 1,000 screened patients positive for a significant lead level, making lead toxicity a sufficiently rare condition to preclude universal screening in accordance with CDC criteria.

There may be a question about the adequacy of our sample size in determining if fixture lead screening is worthwhile. Our data represents the entire first year of lead screening in our Medicaid population. In future years the incidence of elevated leads is likely to be even lower, since all of these children who have already been demonstrated to have normal lead levels will be rescreened. The total number of screenings will increase, with an increase in the size of the denominator and a very small likelihood of an increase in the numerator given the actions already taken to lower blood lead level. Although all of the children in Madison County were not tested, the highest risk group, the Medicaid pediatric population, was tested. Testing of other children in Madison County would not be feasible because these children are covered by different insurance and the results would not be relevant to the Medicaid population. However, the Poisson distribution in our sample of 2,163 patients gives a p=0.1153 (expected 2.163, observed 0). If our sample size were 3,000 (expected 3.000, observed 0), the p=0.0498 and if the sample size were 4,000 (expected 4.000, observed 0), the p=0.0183. Such large numbers can only be obtained by grouping several Alabama counties together. Such an analysis would require better data than the Alabama Department of Public Health can currently collect. Our current data indicates with 88.47 percent confidence (p=0.1153) that further lead screening in Madison County is unnecessary.

Unfortunately, we are unable to report on the remainder of the counties in Alabama. Data from investigations of elevated blood lead levels are not collected systematically from the counties throughout Alabama and are not available for analysis by the Alabama Department of Public Health. Computer software to analyze the available data at the Alabama Department of Public Health cannot provide reliable numerator and denominator data on the lead screening which has been done elsewhere in Alabama, because it would identify as a case any child who had two capillary sticks above 14 mcg/dL. Clinical experience in Madison County suggests that capillary sticks are very unreliable and clinicians only confirm a case positive if a venous stick is obtained. An additional area of concern is the government's requirement to screen children annually between the ages of 6 and 12 months. If a child is screened negative at age 6-12 months, how many additional annual lead screenings are needed to convince the government the child should no longer be screened? Perhaps, as suggested by Pocock et al, screenings should begin at 2 years of age as this is when "blood lead tends to reach its peak concentration"[2]. Continued screening may seem well-intentioned to some in government bureaucracy, but its benefits are less clear to many of us who faithfully try to give conscientious care to the Alabama Medicaid children. Perhaps parents would be better served by educating them about the hazards of lead in the blood and screening their children first using the CDC sample questionnaire shown in Table 2.

Table 2 Assessing the risk of high-dose exposure to lead—sample questionnaire from CDC's *Preventing Lead Poisoning in Young Children.*

Does your child—

1. Live in or regularly visit a house with peeling or chipping paint built before 1960? This could include a day care center, preschool, the home of a baby-sitter or a relative, etc.
2. Live in or regularly visit a house built before 1960 with recent, ongoing, or planned renovation or remodeling?
3. Have a brother or sister, housemate, or playmate being followed or treated for lead poisoning (that is, blood lead greater than or equal to 15 mcg/dL)?
4. Live with an adult whose job or hobby involves exposure to lead?
5. Live near an active smelter, battery recycling plant, or other industry likely to release lead?

In summary, we hope Alabama Medicaid, in conjunction with the Alabama Department of Public Health, will rapidly identify Alabama communities which can be given waivers of the requirement for universal lead screening in children under six years of age. This will decrease unnecessary expenditure of public resources, the children will greatly appreciate the decrease in public mandated phlebotomies, and Alabama will remain in compliance with federal requirements.

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Donna Gosney
A-MASA President

AMA-ERF: Supporting Quality Medical Education

Alliances and auxiliaries across Alabama are planning and implementing steps to participate in one of the most wide-ranging and successful programs promoted by the national alliance, AMA-ERF. The cost of one hour of medical education is estimated to be $21.03. The 1994-95 AMA-ERF campaign urges each medical family to the cost of at least one hour.

But what is AMA-ERF?

The American Medical Association decided in 1953 to form a foundation that would support quality education in the form of grants, scholarships and financial assistance. To fulfill the goal, they created the American Medical Association Education and Research Foundation and sought donations from the members of the AMA. In 1955 they approached the American Medical Association Auxiliary for aid in fund-raising. Since that time, the AMA-ERF has been the only philanthropic endeavor of the AMAA. Through fund-raising efforts ranging from bake sales to golf tournaments the states have contributed more than $2,000,000 a year the past four years. It has become a nation-wide effort with county alliances/auxiliaries competing for awards in monies raised.

How can medical families contribute to AMA-ERF?

1. DONATIONS Many give annual donations in conjunction with their auxiliary dues, donations as memorials or honorarium, or donations in recognition of Alliance/Auxiliary members. The check is made payable to AMA-ERF so it receives full tax deduction status. The donor designates the medical school that will receive the contribution.

The donor can also designate the fund that will receive the money. The Medical School Excellence Fund allows medical schools to use the money where it is most needed. Funds have been used to purchases equipment; subsidize student activities, research projects, guest lectures, and attendance at conferences; and to finance numerous projects that add to the excellence of the medical education experience. The Medical Student Assistance Fund helps students pay educational costs through loans, grants or scholarships.

2. HOLIDAY SHARING CARD In lieu of personal and professional greeting cards, medical families choose to participate in their county Holiday Sharing Card. For a specified donation, their name is added to a card sent to all members of the county medical society stating that the money raised by this card is donated to the AMA-ERF.

3. DIRECT PHYSICIAN DONATION The AMA also solicits donations from physicians. Many physicians make annual donations to their alma mater, and this can be done through the Foundation. I urge physicians to make their donations through their county AMA-ERF Chairman. The money still goes to the medical school of your choice, and the county will receive credit for the donation.

Gifts for AMA-ERF are distributed once a year. No administrative costs are taken out of the AMA-ERF donations. Every dollar goes to the medical schools. In Alabama, the Deans of the four medical school campuses attend the annual convention of AMASA and personally receive the checks for their schools. They have shared

many stories of the ways that the money they receive is used on their campus and the benefits the students gain. They have stated very often that the AMA-ERF donations are not only charitable donations – they are a legacy from one generation of medical professionals to another and an investment in the health of generations to come. County alliances/auxiliaries raised more than $43,000.00 in 1993-94.

If you would like to become part of the effort to support quality education, contact your county AMA-ERF chairman. By participating you let the public know that the medical community is committed to quality health and medical care – and the helps to strengthen relationships between physicians and their patients. Your participation in medical community fund-raisers such as the Holiday Sharing Card, auctions, raffles, and sports events increases awareness of the AMA-ERF, as well as contributions to medical education.

For information on AMA-ERF, contact the AMASA AMA-ERF Chairman Nita Maddox. Physicians who give annually to their medical school, please consider making your donation through your county AMA-ERF Chairman. The money still goes directly to the medical school of your choice and the county will receive credit for the donation.

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Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month – day of month if weekly – and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

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Memo

To: **President Clinton**
Members of the House and Senate

From: **The 300,000 member physicians of the American Medical Association**

Re: **Getting the job done on health care**

We believe there are several workable measures that can be passed now to help achieve our ultimate goal – making quality health care affordable and accessible to all Americans.

As the country awaits the State of the Union address, the member physicians of the American Medical Association set forth these practical recommendations to improve health care for our patients.

Insurance Reform – Pass insurance reforms that will make sure Americans will not lose their coverage if they change jobs or get sick.

Medicare Reform – Reform our Medicare system so it will be there for the next generation of elderly and disabled.

Medical Savings Accounts – Make MSAs available so people can pay for routine medical care with pre-tax dollars.

Patient Protections – Enhance patient choice, disclosure and assure greater physician involvement in corporate decisions about patient care.

Liability Reform – Enact meaningful liability reform to ensure fair compensation to patients with legitimate claims while eliminating excessive malpractice awards that lead to defensive medicine.

Regulatory Relief – Free both physicians and patients from the ever-increasing burden of needless and wasteful paperwork, regulations, obsolete anti-trust rules and red tape.

Medical Education and Research – Protect medical education and research so that we can find cures for killers like AIDS and cancer.

Public Health Problems – Fight social problems like violence and smoking — problems that cost billions of dollars and millions of lives.

These measures are sensible things we can do now that will make a difference for all of us. So, as we begin our nation's 104th Congress, we renew our pledge to the health of America. As the voice of the medical profession, we pledge to do everything we can to help make these things happen. It is <u>our</u> contract with America, and we fervently hope that every American will join us.

American Medical Association
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CONFLICT in Medical Marriages

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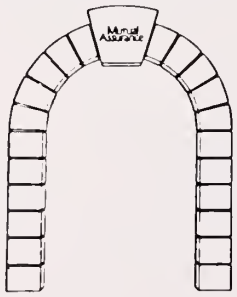
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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Medicare Maulers Beware

You may remember the history of public opinion on health care reform – first, early in the 1992 presidential campaign, and then how the numbers changed as reality began to prevail late in 1993 and throughout 1994.

When it appeared that we would all be getting something for nothing, public support was stratospheric. Then as it became increasingly apparent that reform might cost something, support weakened. Finally, when it was indisputably clear that Mr. Clinton's proposal would cost quite a lot and would result in both collectivization and diminished care for the mass of Americans, support plummeted.

We Americans like bargains: something for nothing is vastly appealing. We are not overly enthusiastic, needless to add, about paying more for less. Thus Clinton care scarcely had a single influential supporter when the end came.

A similar phenomenon can be seen unfolding in public enthusiasm for certain aspects of Newt Gingrich's Contract with America. (Already waggish cartoonists have transformed that into Contract On America.)

First of all, Mr. Gingrich and his supporters in Congress are being somewhat cavalier with the facts when they argue, as the repeatedly do, that "the voters mandated that we do this" (whatever "this" is at the moment) in the last election. The angry voters who threw the Democrats out last Nov. 8 were not voting for the Contract, according to pollsters. Exit polls revealed that 80% of those who voted hadn't even heard of it. Of those who had, few understood the details.

Still, downsizing the federal bureaucracy has wide (if shallow) support as long as it doesn't adversely affect our own lives. And we want lower taxes, along with elimination of wasteful spending. But, getting down to cases, most of us see waste somewhere else. It's great to eliminate this and that so long as we, and our families, aren't affected.

Take, for example, the balanced budget amendment. Great, most of us say – force Congress to live within its means. In the New York Times/NBC News poll at the end of February, 80% of all Americans (82% of those who identified themselves as Republicans and 79% of those who said they were basically Democrats) supported that idea in the abstract.

That's massive support. But look what happened when the pollsters asked the same question but added, "even if it means cuts in Social Security." Support for the amendment plummets almost 50 points, to 32% (40% of Republicans, 25% of Democrats).

This should be pretty solid evidence that nothing much has changed since Mr. Clinton discovered what he should have learned his first year in politics: If it appears essentially free, Americans want it. If it there is a cost, get lost.

Take another example from last year's political campaign and this year's reality: The idea was advanced in the Contract that taxpayers should not pay for supporting unmarried mothers under age 18. But when the question was put to the electorate in February, only 31% would go along with a cut-off; 62% said that unmarried mothers under 18, with no other way of supporting their children, should be allowed to receive welfare.

Here is another aspect of the ambivalence of Americans. Even though there is obviously widespread animosity to "subsidizing teenage pregnancy," when stated in those stark terms by talk show pundits, when it comes right down to letting children suffer, Americans can't stand it.

The GOP Contract also provided for increased military spending. Mr. Gingrich et al fulminated against what they saw as a defense decline engineered by Draft Dodger Clinton. But when the question was put to the people in February, a scant 16% wanted to increase military spending, while 63% wanted spending kept about the same as it is now (and 18% wanted more cuts).

Since all of us want our country strong, what is behind this expression of sentiment? I suspect most people realize that the Congress cannot increase military spending, as promised, while reducing taxes. They've heard that before. They heard it, for example, from Mr. Clinton when he initially campaigned with a promise to give us better health care for less money. He was promising a free lunch; so is Gingrich two years later.

What came out of the February polls was that most Americans believe that Congress should concentrate on jobs and crime; a substantial majority favored a retention of the ban on assault weapons, which Newt has vowed to repeal; and they support Mr. Clinton's legislation to put more cops on the street, an idea rejected by the Newtoids in favor of un earmarked block grants to localities.

Thus eight weeks after the Gingrich revolutionaries assumed control of Congress vowing to make the government more responsive and to implement their Contract, they discover that Americans are very suspicious about major elements of the revolution, and even hostile to some aspects of it. This tends to reinforce the consensus of pundits last November: Enraged voters threw the rascals out, period; they did not mandate all the Republican leadership is claiming.

This brings me to my subject: meat-ax cuts of Medicare to balance the budget and/or to finance the promised tax cut. It should be evident from the February poll that the voters didn't mandate this either, despite the contentions of the revolutionaries.

To chainsaw $1 trillion out of the federal budget in the next seven years, Newt and friends must go after the big bucks. The big bucks are in Medicare: $162.5 billion last year and expected to reach $286 billion in the year 2000, five years from now.

Time magazine (Feb. 27) warns, however, that previous attempts to tinker with the Medicare coverage of 36.3 million aging Americans has given this program the sobriquet, "the third rail of U.S. politics" – touch it and you're dead.

There was big talk last year of achieving the necessary cutbacks by going after the "greedy geezers," supposedly a large group of wealthy seniors, often pictured as frolicking in their yachts off Monaco or Majorca, who should be made to pay their own way.

Surprise! It turns out that 80% of all Medicare benefits go to households with annual incomes of less than $25,000, hardly the yachting set. One Republican proposal being seriously considered is to cap annual outlays, thus borrowing a page from Mr. Clinton's book, allowing nothing for annual growth. But opponents say this would jeopardize the future of hospitals in the inner cities and in rural areas.

Thus, more or less desperate, Republicans are borrowing another Clinton idea, the oxymoronic "managed competition" notion. Whereas some 90% of present Medicare patients go to fee for service doctors, HMOs are suddenly making deep inroads, which the Republicans would encourage.

But there are worries. For example, HCFA says the fed is paying too much for Medicare HMOs. One reason for that is that the sickest of older Americans tend to have two or three specialists they see on a routine basis. The word has gotten to them somehow that they may loose this ready access to specialists if they join an HMO. Since Adam Smith's day we have known that buyers, like sellers, tend to be rational, following their own self interest. A senior citizen content with his/her regular visits to specialists is not likely to opt, unless coerced, for an HMO, where such visits would be severely constrained.

In such HMOs as the Oxford Plan, which is going four bells and a jingle up East, the inevitable consequence is cherry picking. The HMOs tend to get the healthiest, while the sickest in any geographic group remain with fee-for-service specialists.

But HCFA pays HMOs based on some kind of local formula for average costs of a population group, the healthier along with the sicker. If the healthier move to HMOs, this distorts the actuarial formula and actually costs the government (us) more. In other words, the result of the movement to HMOs is adverse selection of the sicker segment, instead of their annual costs being factored into the large population pool. Result: higher overall costs for a given area.

Thus we have another example of how the whole health care financial burden resists and defeats various fixes – change one element and, inevitably, an apparent saving here merely shifts the cost there.

Suppose, then, you force all Medicare patients into HMOs, thus spreading the risks uniformly. But that compulsory regimentation flies in the face of the freedom of choice guaranteed by the Medicare act as well as the Republican promise of an even wider choice for Medicare patients.

Every idea seems to circle the block and return to square one, the same square from which the reform movement was launched years ago.

How will the Republicans escape this box? I don't have a clue, frankly. I think their promise to cut costs and improve the quality of health care delivery places them on the same collision course with reality that, in the end, sank Mr. Clinton's plan.

Secretly, I suspect, at least two people are enjoying the Republican anguish – Ira Magaziner and Hillary Clinton. They've been there.

PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

A Vested Interest in Disaster

As my presidential year approaches its end, nothing seems more urgent to me than the fundamental message that has run through my ruminations in this space: no matter how troubled the landscape of medicine may seem, our profession continues to be the most rewarding of all human endeavor.

It is conceivable, even probable, that medicine will emerge from the present storm cleansed and renewed – rededicated to its historic missions and disconnected from the blasphemous dollar mark.

I concluded my January column: "I believe the glass is still half full." As it happened, the Editor in chief of *U.S. News & World Report,* Mortimer B. Zuckerman, used "The Glass is Half Full" as a caption for his column a few weeks later (Feb. 27, page 80). What he has to say about the prophets of gloom and doom now holding forth applies, I think, to those in our profession who have been declaring the end of medicine.

In fact, his whole column is, to my mind, a metaphor for the current despondency of some physicians.

Mr. Zuckerman is no Pollyanna; he acknowledges the painful adjustments dictated by a rapidly changing economy. Whereas the coming of steam power, the railroad, electricity, the automobile, aircraft, and consumer electronics were all welcome because they increased productivity and spread the wealth generously across the middle class, the new world order, driven by the efficiencies of the computer, telecommunications and all the rest, seems threatening to "members of a morose middle class fearing for their economic future." Mr. Zuckerman:

"On the face of it, the evidence is admittedly gloomy. Technology and global competition have cut into employment in America. The great employers of the 20th century have now become the great unemployers. From 1980 to 1993, the 500 largest U.S. corporations cut payrolls by 4.7 million jobs, a reduction of more than 25%.

"We are not witnessing a temporary blip caused by the business cycle. The downsizing is independent of that. Costs are cut even as the economy grows. And those in jobs do not feel much of a glow. The median income of U.S. households, adjusted for inflation, is down 7% since 1989 alone ... Americans are working harder for less and less and less... Many cannot be sure of a job next year, or even next month...."

That's what the statistics tell his, but there is something phony, Mr. Zuckerman says, about the way such numbers are being crunched. If you look about you, he urges, you will be surprised to see the relative affluence of the typical American, even though the data say he's hurting. One clue to this discrepancy is that the statistics overlook the fact that there has been a reduction in family size. Thus figures showing "family income" are frequently misleading.

"On a per capita basis, discretionary income is up nearly 50% since 1970, even after adjusting for inflation. Non cash income from health insurance, pensions and other fringe benefits has significantly increase real wages.

"There are other signs of good news. Over the past 20 years, the proportion of higher income families has grown faster than the proportion of lower income families.

"It is the way we measure our living standards that yields the curious conclusion that we are living worse rather than better than we did two decades ago. Quality and productivity do not show up in the statistics. New homes are about a third larger than they were a generation ago; they have bigger kitchens and central air conditioning, fireplaces and garages, VCRs and

cable-ready television.

"Many more Americans are finishing high school and college. People are joining the work force later in life and retiring earlier. They work fewer hours and take more paid vacations. Workers, according to one study, have added five years of leisure to their lifetime – three years because of earlier retirement and longer life expectancy. Household net worth has doubled even after adjustment for inflation.

"One reason why perception may not mesh with reality is that inflation itself may be inflated by as much as 50%, says Federal Reserve Chairman Alan Greenspan, which may be why buying power and salaries seem to have declined.

"Why then is the gap so huge between the happier individual experience and the gloomier perception of the economy as a whole? One reason is the new stereotype of the mass layoff, seized on by politicians and by the media that revel in the role of Cassandra.

"But the future looks bright. Productivity seems about to bust out after 20 years of stagnation, powering economic and personal earnings for years to come. American manufacturers have developed the most sophisticated methods of production, turning out goods that are the envy of the world. The United States now ranks as the most competitive economy in the world. We have become they No. 1 exporter."

If all this is true, and Mr. Zuckerman is a responsible journalist, why have the newspapers, television, and the politicians beat us to death with bad news for so many years? The answer is simple: they all have a vested interest in disaster.

The public dotes on scandal, failure, crime, government incompetency and corporate shortcomings. Good news simply doesn't sell. Hence what was once an editorial mindset has become a marketing mindset, pandering to the public appetite for murder, philandering celebrities, dope addicts, crooked lawyers, bad doctors, and economic collapse.

Officerholders are notorious panderers themselves and for the same reasons. If everything is rosy, what would politicians – in office or out – promise to save us from?

The same kind of prevailing negativism has infected our profession. You have all heard the purveyors of professional disaster, those who lament the changing landscape of medicine as proof that we are going down the tube. You've all heard them: they would not advise son or daughter to study medicine because the barbarians have seized the temple.

Perhaps physicians, like the public at large, have been softened by too many years of relative ease and prosperity. Along comes a battery of disruptions in the even tenor of our lives, and we take to the rooftops with cries of ruin.

If we are this weak and easily frightened, is it any wonder that predators in the public and private sectors keep poring it on, reassured by our whining and whimpers that we are pussycats?

Be honest with yourself: can you really imagine any human pursuit more rewarding, materially and spiritually, than serving the sick? I can't. Sure, the intrusions and dislocations are sometimes maddening. But, to my mind, it is all a small price to pay for the pleasure and pride of patient care.

I envy no one, certainly not the managed care moguls who have only money to show for their earthly existence. I am enriched by a satisfaction that cannot be measured in dollars – the transcendent satisfaction of knowing that I have served humanity and that the world is just a little bit better for my life in medicine.

I wouldn't trade that for a kingdom. And, yes, if I had it to do all over again, I would hesitate no longer than a nanosecond to choose medicine for my life's work. I pity those doctors who feel otherwise.

Pericarditis Following Blunt Thoracic Trauma

*by Donald R. Smith, M.D.**

ABSTRACT

Pericarditis is a common clinical entity which has been reported frequently in association with numerous disease processes. However, pericarditis following blunt thoracic trauma is exceedingly rare and difficult to diagnosis. An 18 year-old female was transferred to UAB Hospital for evaluation and management of multiple injuries following a high-speed single-vehicle motor vehicle accident. Injuries included a fractured right tibia and femur, pelvic fracture, and a right pulmonary contusion with rib fractures. Orthopedic procedures were performed. Ventilatory support was provided due to a severe pulmonary contusion. The post-operative course was unremarkable. The patient was discharged two weeks after admission. One week after discharge, the patient was readmitted with pleuritic chest pain of several days duration. Diagnostic studies were performed. The patient was successfully treated with non-steroidal anti-inflammatory medications for pericarditis. Dramatic improvement ensured over two days. Follow-up showed no recurrence of pericardial symptoms, pleural effusion, or chest pain. In retrospect, complaints of episodic chest pain which were felt to be clinically insignificant during admission, may have been early signs of post-traumatic pericarditis secondary to blunt thoracic trauma.

INTRODUCTION:

Pericarditis is encountered frequently in association with chronic medical conditions. However, the occurrence of pericarditis in the setting of trauma is rare and most frequently results from penetrating mediastinal injuries. Successful treatment requires expeditious diagnosis and institution of therapy to prevent the ominous complications of pericardial effusion and subsequent tamponade. Proper management depends upon differentiation of posttraumatic pericarditis from other medical conditions such as pneumonia, pleuritis, pleural effusion, myocardial infarction, and pulmonary embolus. The variability with regard to onset of symptoms makes diagnosis difficult in the setting of multiple serious injuries

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CASE REPORT:

An 18 year-old female was admitted to a regional hospital following a high-speed single-vehicle motor vehicle accident. Injuries included a right pneumothorax, fractures of the right fourth, fifth, and sixth ribs, diastasis of the pubic symphysis, and closed fractures of the right femur and tibia. A large-bore chest tube was placed in the right chest. The fractures were mechanically stabilized for transfer to the University of Alabama Hospital for further evaluation and treatment.

On arrival to UAB Hospital, the patient was hemodynamically intact. Vital signs and pulmonary function remained stable throughout the initial evaluation. Physical examination showed diminished breath sounds on the right side, a stable, but tender, pelvic examination with profound tenderness over the pubic symphysis. Heart sounds were normal. Abdominal examination showed no peritoneal signs and no distention. The patient had a grossly deformed right femur and tibia without evidence of open fracture. Laboratory values were significant for a hemoglobin of 11.5 mg/dL, and an arterial PaO_2 of 74 mm/Hg on two liters 0_2 by nasal cannula. The patient had a progressive increase in her respiratory rate over several hours which necessitated orotracheal intubation. Chest radiograph showed no pneumothorax and an intraparenchymal position of the previously-placed pleural tube. This tube was removed and a proper right-sided tube thoracostomy was performed. Repeat chest radiograph showed a right upper lobe pulmonary contusion and adequate placement of both endotracheal and chest tubes.

The following morning, corrective orthopedic procedures were performed for the lower extremity fractures. The patient required prolonged ventilatory support post-operatively due to continued respiratory insufficiency. The patient was transferred to the floor one week later. Approximately one week after transfer to the floor, the patient was discharged and scheduled for follow-up.

Seven days following discharge, the patient was readmitted with complaints of nonspecific right-sided chest pains, rapid heart rate and difficulty breathing. Physical examination was significant for diminished breath sounds on the left chest, coarse breath sounds over the right chest, and normal heart sounds. No pericardial friction rub was noted. Chest x-ray revealed a left pleural effusion and a normal cardiac

silhouette. Electrocardiogram on admission was normal. A repeat electrocardiogram on the second admission day, after complaints of substernal chest pain, revealed characteristic findings of pericarditis. Echocardiogram was normal with no evidence of pericardial effusion or dyskinesia. Pulmonary ventilation/perfusion scan was of low probability thereby ruling out pulmonary embolus as the cause of chest pain.

Therapy was instituted initially with ketorolac 60mg IV followed by ketorolac 30mg IV Q6hr for 48 hours. Dramatic improvement of symptoms ensued and the patient was discharged two days later. Discharge medications included indomethacin 25mg PO three times a day.

Follow-up one week after discharge showed resolution of the left pleural effusion, no residual pulmonary contusion or pneumothorax, and no recurrence of chest pain.

DISCUSSION:

Pericarditis is a common clinical entity. The incidence cannot be reported with certainty as most cases are subclinical with diagnosis made at autopsy more frequently than in life[1]. The overall incidence of pericarditis in a multiple trauma patient may be more frequent than previously reported due to the subclinical, and most often, self-limited nature of the disease. The severity and prominence of associated injuries to other organ systems may obscure the recognition and delay the diagnosis of pericarditis in trauma patients. A full description of all the possible etiologies of pericarditis is beyond the scope of this review. Therefore, clinically salient points as related to thoracic trauma patients are discussed.

The literature surrounding the incidence of pericarditis following closed chest trauma is scant. Constrictive pericarditis can result from both blunt and penetrating trauma to the chest, with acute penetrating injury to the heart being most commonly reported[2]. Pericarditis secondary to penetrating pericardial and cardiac trauma has been well documented[3]. Clinical characteristics are similar to those encountered in the post-pericardiotomy syndrome following cardiac surgery[4]. Signs of pericarditis following pericardial and chest trauma include congestive heart failure, equalization of diastolic filling pressures, characteristic dipplateau of the right ventricular wave form on cardiac catheritization, and tachycardia with associated tachypnea exacerbated by recumbent positioning[5]. Constrictive pericarditis typically occurs within two to four weeks following penetrating injury to the pericardium. This time of onset may be variable depending on the precise etiology. Viral syndromes and trauma-related etiologies cause symptoms and signs to occur earlier in the clinical course than do pathologic changes associated with malignancy and chronic illness. Months to years may be necessary for the development of clinically significant pericardial complications.

Few cases of pericarditis secondary to blunt thoracic trauma have been reported in the literature. Van-Vooren, et al reporting a case of purulent pericarditis resulting from blunt chest trauma associated with a staphylococcal endocarditis and valvulitis[6]. The cause and effect temporal relationship of these disorders remains to be elucidated. Pericarditis has also been reported following chest trauma in patients with pectus excavatum, hepatic trauma requiring pericardiotomy, for vascular control, and in patients sustaining parenchymal lung injuries[7,8,9].

Both autoimmune and virologic factors have been implicated in the etiology of pericarditis following blunt chest trauma[10]. In our case, the presence of lung injury with parenchymal disruption due to the improper placement of a pleural tube may have contributed to the development of pericarditis. This contention is supported by previous articles which demonstrate clearly that the release of various tissue factors can incite inflammation[11]. Antigenic stimulation of an inflammatory reponse by the release of lung parenchymal tissue factors is proposed as a possible inciting source in the development of pericarditis in our patient. Similar to local hemorrhage and tissue destruction that causes focal inflammation in areas of pulmonary contusion and in processes such as the adult respiratory distress syndrome, the heart can act as a source of inflammatory mediation. If our patient had suffered a subclinical myocardial contusion, without lung injury, subsequent antigenic release and immunologic response to cardiac and pericardial tissue factors and antigens could have been responsible for the sustained pericardial inflammatory reaction resulting in pericarditis. Release of tissue factors from lung parenchyma as well as pericardial tissue has been implicated in the autoimmune response to tissue injury[12]. In the absence of an obvious infectious source or cardiac contusion with hemopericardium, either autoimmune or idiopathic etiologies should be considered in patients with thoracic trauma. In our patient, the presence of a substantial left pleural effusion coincided with the onset of the pericardial symptoms. The relationship uncertain but a temporal relationship is suggested as the pleural effusion rapidly resolved once treatment for the inflammatory process was instituted.

The diagnosis of pericarditis in the absence of classic signs and symptoms, as in the case of our patient, is one of exclusion. Pain is one of the most important clinical features of pericarditis. The pain is typically substernal and pleuritic in nature with exacerbation during inspiration and recumbency.

Varying degrees of electrocardiographic abnormalities can be demonstrated in acute trauma-related pericarditis. ST-segment elevation, T-wave inversion, and variably shortened PR intervals can be seen throughout all leads. These changes quite commonly follow within hours of the onset of chest pain and can occur in different sequences depending on the etiology of the pericarditis.

Radiographic evidence supporting the diagnosis of post-traumatic pericarditis include, but is not confined to, the presence of a widened mediastinum, increased opacity and enlargement of the cardiac silhouette,

pleural effusion, globular heart, and associated pulmonary contusion. Echocardiogram is the most sensitive method to demonstrate the presence of intrapericardial effusion and nonspecific pericardial inflammation. These studies should be employed in the presence of abnormalities found on physical examination, EKG, chest radiograph, and laboratory values in patients following blunt thoracic trauma. In the case presented, the patient did not demonstrate wall motion abnormalities nor pericardial effusion consistent with new onset pericarditis following chest trauma. However, just prior to institution of nonsteroidal anti-inflammatory therapy, the patient did demonstrate ST elevation and T-wave inversion in the lateral leads of the electrocardiogram.

Treatment of diagnosed pericarditis resulting from blunt thoracic trauma is similar to that utilized for pericarditis in other conditions. Analgesics and anti-inflammatory agents are the mainstay of medical therapy. These agents are usually started after surgically correctable causes of pericarditis have been ruled out (i.e. pneumopericardium, hemopericardium, purulent pericarditis, extrapericardial foci of inflammation, and mediastinal foci of inflammation). Initial therapy traditionally consists of nonsteroidal anti-inflammatory medications (i.e. ketorolac, ibuprofen, indomethacin, etc.) in three times per day or four times per day dosing intervals. The doses necessary for amelioration of symptoms may be tapered after the patient has been asymptomatic for five to seven days.

The use corticosteroids is controversial. Hancock and associates reported a 10%-20% rate of recurrence of symptoms in patients in whom dosage was tapered to less than 10mg - 15mg of prednisone per day . This poses a particular problem in the withdrawal of treatment with corticosteroids.

CONCLUSION:

Pericarditis is a common clinical entity and can be seen in association with numerous disease processes. Its occurrence in blunt thoracic trauma is exceedingly rare. This rarity is evidenced by articles such as those of Rice et al which reported only sixteen cases reported in the literature prior to 1980[13]. These cases of pericarditis were not isolated simply to blunt thoracic trauma but included cases related to penetrating cardiac and mediastinal trauma as well as cases of pericardiotomy syndrome. Though it is exceedingly rare, pericarditis associated with blunt thoracic trauma carries the same ominous potential for complication as those encountered in non-traumatic instances, namely pericardial effusion and tamponade. Successful management of this condition and patient outcome is dependent on prompt consideration of this entity in the differential diagnosis in the trauma patient. This is particularly applicable to patients suffering multiple injuries. The more obvious severe injuries in multiply traumatized patients may predominate during the management, thereby allowing this often subclinical entity to go overlooked and underestimated in clinical significance.

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Dying, An Important Phase Of Living

*by Ernest S. Campbell, M.D., F.A.C.S.**

One has to have some admiration for those physicians who have the courage of their convictions to espouse points of view at odds with current thinking even though you might be completely at odds with their particular stand. I'm thinking in terms of highly emotionally charged ethical topics such as abortion, genetic manipulation, or physician assisted suicide. It doesn't take much to push someone's button leaving that person at total loss of rational thought able only to engage in personal insults. Here are some thoughts on death and dying which I can now bring forward without fear of professional recriminations.

This is definitely what has happened with the abortion debate, is well on it's way to happening with the question of genetic manipulation, and the courts can't seem to keep their hands off the assisted suicide question. All of these topics relate to individual choice as opposed to governmental interference.

Dr. Jack Kevorkian, or "Dr. Death" as he has been so luridly called by the media, has continued to be the topic of newspaper headlines and television segments as he has persisted in his quest to make humane euthanasia a suitable choice for the dying and suffering individual. Although I have mixed emotions about this man personally, feeling on the one hand that he is a publicity-seeking pathologist who has never taken care of a suffering, dying patient (only the dead), obversely I admire his courage in facing down the powers that be — the Michigan state legislature and Attorney General's office; the stated point of view of the AMA and many of his medical peers.

All of us have had terminally ill patients for whom dying would have been much more preferable to the continued pain and suffering imposed by their illness. Like most other mainstream physicians I attempted the skillful use of palliative care rather than Kevorkian's methods. Yet on the other hand, the realities facing the dying patient are not well faced by legal obligations, societal reprimands and oversimplified ethical solutions imposed as a broad brush by those not intimately acquainted with the problems posed by each individual case.

Perhaps Dr. Kevorkian has rendered all of us a service by focusing attention on the whole spectrum of dying and the real issues behind doctor assisted suicide. This problem is not the sole province of the medical profession — most of us are fearful of death and society has developed a complex ritualization of myth to rationalize death. Doctors have been taught that the death of a patient was tantamount to defeat and that the dying patient must be kept alive at all costs (literally).

Some of us however, would consider the "process" of dying much more fearful than dying itself. We fear the thought of unbearable pain; fear the loss of control of ourselves and our bodily functions; fear undergoing treatments that may or may not be helpful or that actually may be harmful. Some of us fear being alone at the end of our lives in an unfamiliar setting and some of us sense that we are an inconvenience to our families; others of us possibly have no families or loved ones to help us at the end. The release of death is often prayed for by the patient, and all of us (doctors) usually can only stand by giving more sedatives, morphine and IV fluids, subconsciously wishing that we could help the patient in some other way.

It is no wonder that a deliberate act of leaving this life or assisting one to leave has an appeal —especially if one is aided by a caring, supportive power figure such as a doctor who the patient trusts and who makes sure that there are no slip-ups in the act. Yet there are those who feel that assisting in the ending of a life is not and should never be an extension of a physicians' role. To intentionally cause death is anathema to all doctors, and physician assisted suicide, physician controlled executions, and abortion seem to contradict all that we have been taught and stand for.

Perhaps one could conceive of a time in the future when society will think differently of death and dying; when survival of the species might depend on control of overpopulation; a genetically manipulated time when no one has parents or the guilt involved with parental death; albeit a time when the state may have to make hard decisions concerning length and quality of life. However, this is now and personal choice continues to be an option, at least in our Western civilization.

Like him or not, Dr. Kevorkian has tenaciously persisted in his quest for the right to help dying people kill themselves. The state of Michigan has been just as persistent in attempting to circumvent Michigan court rulings which have supported Dr. Kevorkian's position.

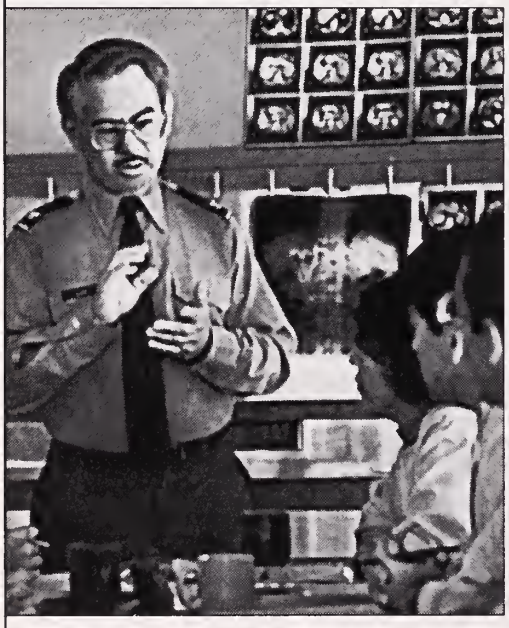
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Legal or not, assisting at the suicide of a patient is felt by most physicians to be unethical. Whether or not Dr. Kevorkian is right or wrong is not as important as is the focus that has been placed on the problem of dying. Maybe this focus will cause doctors to push harder at trying to make the final days of "living" more comfortable and pain free.

The usual scenario of hospital dying is that of one or more specialists applying their respective skills to the utmost until the end of curative treatment. This usually signals the end of open dialogue between these doctors and patient, who generally has some sense of abandonment. It is at this point that the patient can be helped the most by personal support from his family physician, hospice, and friends and loved ones. Frank discussions of outcomes, possible further treatments, and advanced directives, can give the patient a measure of control over his life if and when he is unable to communicate due to his illness. The hospice movement has become outstanding in it's ability to bridge the gap between hospital bed and home care, allowing many patients to pass their final days in a loving environment with their families.

It is a good cathartic to be able to debate these issues in a forum such as [this].Open discussions of these ethical issues are rarely broached in hospital medical staff meetings and doctors lounges for fear of alienating associates and referrers; consequently they get shunted to the op-ed pages of specialty society journals, and usually are stiffly-written opuses by professors or medical students with little actual experience dealing with death and the dying. Experiencing the death (or the passage of life from a body) of an individual for whom you have feeling, is an awesome thing, not to be trivialized by societal, legal or governmental meddling. Prolongation of this experience, however, should not be undertaken without fully exploring all the options with the patient and his family.

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Conflicts In Medical Marriages

*by Donald Rosen, M.D.**

Donald Rosen, M.D., is a psychiatrist with the Menninger Clinic, Topeka, Kansas. He has extensive professional experience with conflicts in the medical marriage and is eminently qualified, as this paper illustrates. Few physicians could not identify with the physician traits elicited by Dr. Rosen and how these traits have the potential to impact upon the medical marriage and family of the physician. If read carefully and kept for future reference, this presentation will have a positive impact for the reader.

G.L. Summer, M.D.
Medical Director
Physicians Recovery Network

This group is probably the last group that needs to hear that medical practice is becoming harder. It's becoming more stressfull with each new change that we physicians encounter— whether that change is dictated by the Joint Commission, whether that change is dictated by federal or state agencies, or whether that change is dictated by the impending health care changes that are undoubtedly going to affect us all in ways we can't begin to predict. All of these have an impact on the enjoyment of our work, and each takes time and energy away from our work. Malpractice claims and their implicit demands for perfect outcomes every time pose yet, of course, another threat to our morale.

I'm here today to talk, not about managed care, mercifully, but instead to talk about the most important relationships we have in our lives, and that is the medical marriage because our marriages are in a paradoxical position. Marital relationships can be the first casualty of the stress of a medical practice or the medical marriage can be the most important coping mechanism for the stress of a medical practice. The remarks that I have prepared for today are based largely on my work with two colleagues of mine, Glen Gabbard and Roy Menninger. Our data is compiled largely from our workshops that we've presented in Crested Butte, Colorado, for a week-long workshop entitled, "Physicians and Their Families". I'd like to point out that the participants who involved themselves in our studies were all self-selected, psychologically healthy, and adequately functioning—about as "normal" as I dare to say we get—although I realize I'm taking liberty with the term. It was interesting because our study led us to conclude that it was the psychological characteristics of physicians that were of central importance in the development of the typical conflicts that existed within a medical marriage. In a way we discovered that medical training selects out those that with certain personality traits. Unlike many other careers, becoming a physician is something that many of us dream of during childhood or adolescence long before we go to college. As you all know, it takes a significant amount of dedication and focus to stay on track through the vicissitudes of adolescence, the demands of seemingly endless college courses, and the trials of an even more endless medical education, so, of course, the dedication and focus that we bring to our work is in part an outgrowth of that same dedication and focus that gets us through our training. Long days, long weeks, and short vacations are, of course, much more often the rule than the exception. Although we are to some degree an heterogeneous group, there are some particular personality traits that are more frequently found than others and are of central importance for our discussion here today, such as the presence of obsessive/compulsive personality traits. These traits may make us wonderful physicians but they may make us problematic spouses.

I have seven basic points that I would like to make about obsessive/compulsive traits. I'm sure that after I am done speaking you will agree with me that seven is the exact number needed to talk about obsessive/compulsive traits, that six traits would be woefully insufficient, and that eight traits would be unnecessarily redundant! So, seven, here we go.

Perfectionistic: Compulsive physicians — present company excluded — tend to be very perfectionistic. We tend to be demanding and impatient, chronically unsatisfied with our own efforts or the efforts of others. I used to play quite a bit of tennis. I was playing doubles one time and the ball came to me and I hit it wide. I went over to my partner and I said, "Oh, I'm sorry, I'm sorry. I should not have done that. I feel terrible." A few points later I hit one into the net: "Oh, I'm sorry, I'm sorry I hit the backhand into the net." A few

*Presented in Atlanta, Georgia August 3, 1994. Transcribed and reprinted with permission of the author.

points later, I double fault: "Oh, I'm sorry, I'm sorry." He finally looked at me and said, "Look, Rosen, you are not good enough to apologize like this." Well, as he so diplomatically pointed out to me, it was not his perfectionistic demands of me that were getting in the way, it was my perfectionistic demands of me that were unrealistic and intolerable to myself.

The second trait of compulsive physicians is that we tend to be **workaholics**, and people overwork for a variety of reasons. It is not just one reason and I challenge us all not to simplify it in that way. In fact, I would like for each of you to think about it — those of you who do work too much—why do you do it? Here are some hypotheses. Some people overwork as a means of expiation of guilt. They feel bad about something. What do they do with their guilty feelings? They try to atone for it by channeling it into work. Some people overwork as a means of absorbing anger. They don't deal with the feelings of anger—they get angry, they work harder. I've seen myself do this a lot of times. Some folks who feel that they are in need of ultimate approbation and love, who have never really gotten the kind of care and nurturing that they are looking for, will just say to themselves, "If I work hard enough, I know I'm going to get it." So, they become workaholics as a means of trying to earn some kind of ultimate approbation and love.

The third trait of us compulsive physicians is that we tend to be markedly **guilt prone** and we ceaselessly invoke what we have come to call the "not enough" litany. The "not enough" litany has a higher component to it. For instance: "I'm not taking good enough care of my patients. I haven't done enough, well enough, soon enough. I haven't read enough. I don't spend enough time with my kids. I don't do enough with my wife." And of course sadly and often very much the least, "I don't take good enough care of myself."

The fourth trait is an **exaggerated sense of responsibility**. Guilt prone physicians tend to be overly responsible for their patients, and again, it is good for the patients but very hard on us and our families. It also leads us to feel that anything that happens to our patients is our fault.

The **limited capacity for emotional expressiveness** is a prime characteristic of obsessive/compulsives. Physicians tend to be emotionally constricted. They have difficulty enjoying or tolerating strong feelings—not just negative strong feelings, but positive feelings as well.

Closeness and intimacy: We tend to avoid closeness and intimacy because when you are in close and intimate relationships you tend to have strong feelings. If strong feelings are not tolerable, you tend to back away from relationships where they might be felt and experienced and have to be dealt with.

Lastly, the seventh and final characteristic of obsessive/compulsive folks is that we tend to **not get much fun out of life**, or it's only possible when one makes work of it. A fellow who's a friend of mine, a physician, goes on vacation. Every day at the end of the day, on vacation with his wife and kids in the hotel rooms, he takes out a blank piece of paper and he writes down what they spent their money on that day — how much in amusement, how much in food, how much in hotel, how much in gas, everything — and he totals up how much they spent. Then in a separate ledger he writes a total of what he would have made if he had been working that day — and then he presents his wife with his sacrifice. I'll spare you her response.

Our obsessiveness places us in a paradoxical position because the personality characteristics that make us good physicians are also the ones that produce marital trouble. For instance, we tend to be thorough, careful, and hyper-conscientious. We tend to go the extra mile for our patients. We have a deep commitment to our work and we regularly suppress anger or other negative emotions that get in the way of our clinical effectiveness.

I think the best study of how physicians tend to become obsessive/compulsive, or how obsessive/compulsive people tend to drift into medicine, has been done by Dr. George Vaillant and his group at Harvard. Dr. Vaillant and his group studied forty physicians and seventy-nine matched control groups beginning when they were sophomores in college before anybody went to medical school. Here's what they found: People in his study who went on to become physicians experienced similarities in childhood. One of the similarities they experienced was that they were raised in homes where they *perceived* they were given an insufficient amount of nurturing and support. I underline the word "perceived" because this is not meant to be an indictment of what parental behaviors actually were, but rather a statement of recognition of what the child's experience or perception of those parental behaviors were. This background lead them to develop a sense of residual doubt about their own lovability and self-worth. Future physicians were raised in homes with high parental expectations — not always spoken expectations, but high parental expectations — and they developed a belief that hard work, self-sacrifice, and the attainment of perfection will finally get them the love and approbation that they have been seeking all these years. Now if you have this constellation, it is easy to see how anger and hostility would be suppressed and conflict would be avoided for fear that the direct expression of conflict would risk separation from these somewhat tenuous sources of nurturing and support. Consequently, we physicians have extreme difficulties with dependency. We make lousy patients, you all know that. You see, our dependency needs are secretly sought, but conscientiously it's too painful, so we deny them. This leads us to convert our

concern about getting our nurturing needs met by others to providing nurturance for others — I don't need help; my patients need help and I'll be there to help them — thus shifting the focus of control from getting our nurturing needs met, from depending on others, to giving to others. Only it doesn't really work. It's like trying to get your dependency needs met by proxy or vicariously through others.

The other group that I see this a whole lot with is ministers. I work with a number of ministers who have attempted to get their wishes to be ministered to met by ministering to other people.

As I said earlier, compulsive physicians tend not to get much fun out of life and it's often only possible if we first make work for it. For example, one doctor when preparing for a vacation said, "First, I must get all of my paperwork up-to-date, even though this means working five successive nights until two a.m. Then I've got to be sure that all the loose notes and memos piled on my desk have been properly filed and disposed of, and that I've left referral memos to all of my colleagues who'll be covering for me that will anticipate every possible contingency that might arise while I'm gone. Then I set aside the articles and books that must get read while I'm on vacation to make sure that every moment of my leisure time is well and fully utilized." Our patients are not likely to complain about our compulsiveness. They appreciate our thoroughness. Here's the doctor and the patient and the doctor says, "Well, Bob, it looks like a paper cut, but just to be sure, let's do lots of tests." Nor are we, ourselves, likely to complain about our own compulsiveness. After all, we love to work. Here's the workaholics bar: there's the bar and there's the barkeeper and he says to one of the workers, "That's it pal, no more work for you!"

Let's face it, most of us if ill would want a compulsive physician taking care of us. It's spouses and children who are the ones who are most likely to receive the main impact of our compulsivity and they are the ones who are most likely to complain. Here's the male doctor checking in and she says, "I'm your wife, Arthur. You don't talk to me. You don't 'touch base' with me." Even when the physician gets home, we are as likely to put on our jogging suit and head out the door as we are to sit down and spend time with our spouses. Here's the spouse in the far room and the doctor heading out the door and she says, "You can run, Elliott, but you cannot hide."

A lot of doctors' spouses feel like single parents, and most physicians feel chronically guilty about the lack of time they spend with their children. "Dad, here's that update on my childhood you requested." To our credit, we physicians are often quite resourceful in thinking of new and creative ways to spend time with our kids. Here's a child in bed and dad's on the VCR, sitting next to the bed and he says on the video,



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"Pleasant dreams, Billy, and here's daddy with one of your favorite bedtime stories."

Studies of medical marriages indicate that many physicians and spouses lead what Thoreau called "lives of quiet desperation." In Dr. Vaillant's study, he reported that 47% of physicians versus 32% of controls reported unhappy marriages. Interestingly, physicians tended to stay in unhappy marriages rather than divorce. Male physicians have a slightly lower divorce rate than men of comparable age in the general population. Female physicians get divorced twice as often as male physicians, but less often than other female professionals or the employed female population as a whole. Given that studies document a greater degree of unhappiness in medical marriages, we sought to answer the question: What's the source of the unhappiness? Our study confirmed the data from other studies, and it was surprising to me that studies show no correlation between long hours at work and degree of marital discord. In fact, the lack of time in the marital relationship appeared to be more of an excuse. It appeared to be an externalization of issues that existed inside the marital relationship onto factors outside the marital relationship. Far more important in the development of conflicts in marriage were the physician's psychological characteristics that I went over earlier.

I'll begin this part of my discussion by talking about the male physician's marriage. This portion of our study consisted of 125 spouses and 134 physicians, 111 of whom were married to each other. While only 29% of the physicians and spouses said that they were dissatisfied with their marriages, 47% said that they had sought marital counseling and another 21% reported having seriously considered it, for a total of 68% of the physicians and 65% of the spouses that had either sought or seriously considered marital counseling. Despite the high percentage of marital counseling, again only 29% said that they had seriously considered separation or divorce. One doctor's wife, interestingly, on her questionnaire in response to the question, "Have you ever considered separation or divorce?" replied, "Murder, yes — divorce, no." All physicians and spouses rank-ordered what they thought were the greatest sources of conflict in their marriage. While lack of intimacy was rated very highly as a source of conflict for the spouse, the male physician ranked it very low. Compulsive physicians tend to have great problems with intimacy so we don't feel a great need for it. The male doctor's wife, on the other hand, is another story. One wife said, "Sometimes when I hug him, I feel there's no one there and this scares me." Again, long hours at work were often cited as the problem, but our study confirmed the data from other studies: that there was absolutely no correlation between long hours spent at work and degree of marital gtification. In fact, those physicians who worked more than 60 hours per week were no different than those physicians who worked 40-50 hours per week in terms of degree of marital gratification. Those doctors who worked more than 60 hours per week tended to have more frequent sexual relations with their spouses than those who worked 40-50 hours per week. We asked physicians to rank-order their major complaints about their spouses. Number one: "Is not interested in sexual activity." Number two: "Doesn't empathize with my role of physician." And number three: "Doesn't listen to me." We asked spouses to rank-order their major complaints about physicians. Number one: "Doesn't talk to me enough." Number two: "Doesn't provide enough emotional support for me." And number three: "Doesn't listen to me." The high ranking of "Doesn't listen to me" by the physician and "Doesn't talk to me enough" by the spouse might imply that one of the reasons doctors don't talk to their spouses as much as their spouses would like is that they don't feel listened to.

We concluded from our study that the lack of time due to the demands of our clinical practice is more of a symptom of marital problems than the cause. Our study suggested three major sources of conflict in a medical marnage: l) differing needs for intimacy, 2) differing perception of the problems in the marital relationship, and 3) different communication styles.

First let's talk about differing needs for intimacy. A compulsive doctor feels much less need for intimacy than his spouse. The result is that the spouse may experience a sense of isolation and loneliness. For example one wife said on our study, "I realize through this study that there is no one with whom I share my inner-most feelings and I had wondered why I felt so lonely. I guess that's one of the answers. You see, my dream was that my husband would be my best friend, the one to share all with, and I started our marriage that way. But after one year of courtship and about five of marriage, I realized that all of my talking, sharing, and feeling was falling on deaf ears, so I stopped trying." The physician who works incredibly long hours, in fact, may be over-working in order to avoid the emotional closeness at home where we lack the clear role boundaries of the professional doctor/patient relationship.

Second, spouses have differing perceptions of the problems. Physicians and spouses disagree entirely about the sources of conflict. From a statistical standpoint there was no correlation that we could use. Mike and Linda were a couple who once sought marital counseling who nicely illustrate this tendency to have differing perceptions of the conflicts in their relationship. Mike is a 44 year old orthopaedic surgeon and Linda is a 42 year old homemaker. On their first visit to me, I asked them to outline what the problems were that brought them to therapy. Linda complained that she needed more intimacy with Mike. Mike said he

needed more freedom from Linda. We're off to a good start. Linda said that Mike was never home when supper was ready. Mike said that he couldn't be home at six o'clock and rush through rounds just so he could be home when dinner was on the table. He said that he had built his practice by spending time with his patients and listening to them and he simply couldn't rush his practice just to get home and be with her at dinner. See, Linda insisted that the demands of the practice really weren't the problem. She said, "Even when he is home, he doesn't spend time with me." Mike exploded at this point, feeling that he had been unjustly accused. "All she wants to do is watch TV. I hate TV. I like to read." Linda says that her idea of spending time together is sitting next to each other on the sofa, cuddling up close and chatting as they watch TV. Mike's idea of spending time together was his reading a book in one room and Linda reading a book in another room. So I asked the couple what they did together for fun. Linda said that she couldn't remember a single time in the past year where the two of them had done something for fun together. Again Mike objected. He cited several occasions where the two of them had spent evenings together with friends playing cards. Again they expressed their ideas of what spending time together meant in a very different way. For Mike, they were doing something together if friends were with them. For Linda, if they were doing something together with friends they really weren't doing something together. The long term consequences of these differing needs for intimacy were that Mike tended to distance himself more and more by staying away from home and not telling Linda where he was. And of course, Linda's response to this was to pursue Mike all over town by trying to chase him down via phone calls. Ultimately, Linda walked in on Mike in a motel room with another woman. This is an example of distancing and pursuing. They have two very differing needs for intimacy. As Linda would move closer to make herself more comfortable, Mike would feel less comfortable and reset the distance. She'd move closer, he'd move away. She'd move closer, he'd move away. Ultimately it became intolerable for the two of them.

Some spouses find that the only form of intimacy they can attain is if they take the role of being their spouses' patient. They get their husbands' attention by a myriad of physical and psychological complaints. One of the most extreme forms of this doctor/patient form of marriage came to my attention a few years ago in our hospital. I was treating a depressed 46 year old family practitioner's wife who had been hospitalized for suicidal behavior. I felt unable to treat the patient because the patient's husband demanded complete control over the use of all medications and consultants. For twenty years, he told me, he'd been completely responsible for her medical care—pap smears, ob care, everything. She had been on anti-depressants prescribed by him prior to coming in for treatment and, in fact, had overdosed on them shortly before admission. After considerable work—some of it diplomatic, some of it not so diplomatic—he gave up control over the use of medications and finally let me do my job. What happened? His wife promptly overdosed again. What was the message that I learned in this? I learned that, for this physician's wife, even though she said that she desperately wanted change, at some level she was quite threatened by it.

Third is the differing communication styles. Spouses, as you would predict, showed a distinct preference for the verbal expression of feelings. Physicians, on the other hand, demonstrated a preference for the physical or sexual mode of expressing feelings. In short, when the physician wishes to make love, his wife wishes to talk. The two are communicating in entirely different languages that often miss each other completely. Another frequent situation is that the more emotionally expressive the physician's spouse gets, the more the physician shuts down. And of course, marital couples know what weapons to use against each other. When the wife is mad, she withholds sex and when the husband is mad, he withholds conversation.

Strains in communication may become particularly noticeable during times of crisis; like a malpractice suit. Phil is a 56 year old, highly respected, physician who was sued for malpractice. Even though it was a nuisance suit, Phil was devastated when it was published in a local paper. Although his colleagues said nothing to him about the suit, he was haunted by fantasies about what they thought. He stopped spending time in the doctor's lounge, began to withdraw, lost all interest in sex, and developed severe insomnia. His wife begged him to talk about it. Instead he brought home copies of depositions for her to read. When the therapist asked Phil if he told his wife what his worst fears were, Phil said, "I think she knew what my worst fears were." It's often said, as you know, that physicians speak the language of logic while their wives speak the language of emotion, but I tell you, this logic can be only skin deep at best. You see, Phil's response conveyed a highly illogical form of magical thinking. He expected his wife to know what he was thinking and feeling without him having to tell her. That kind of dependence on mind reading is a common source of conflict in a medical marriage. In a similar way, physicians often expect their emotional needs to be taken care of without having to ask. The diagnosis of a problem as a lack of communication is perhaps somewhat of a misnomer. You know, one can't "not communicate." Everyone communicates. What I think people usually mean when they say, "We have a communication problem," is that they don't like what it is their partner is communicating and how it is being communicated.

I'd like to talk a bit more for a moment about malpractice claims because they are so cutting to the core

of our compulsive dynamics. What are malpractice claims? They are allegations of the four D's. They are Dereliction of Duty that Directly leads to Damage. Now for someone who is perfectionistic, has a strong sense of guilt and doubt, and an exaggerated sense of responsibility, it is a devastating experience. The impact on the marital relationship and on marital communications is, of course, profound. First there is the stress of the litigation, which, as we all know, is a seemingly endless process. The serving of papers, the assault on everyone's sense of identity and integrity—these pose an often unprecedented threat to the psychological health of the physician. We see typically two major responses within the doctor: anger towards others and towards the self. I did an evaluation on a fellow who came to my office at the behest of attomeys and his state board. He was sitting in my office going "I did this, and I did this," and he gave a very factual reporting of what happened until he got to the point of the description of what it was that he was there to talk about, at which he said, "I'm so stupid, I'm so stupid, I'm so stupid, I can't believe I did this." And I was just like, "Would you just shut up and tell me what you did before you go on with this castigation." But he was so angry at himself and so angry at this woman who was filing this complaint against him that it was destroying him.

The other major response is a sense of isolation. Most doctors feel incredibly alone with their experience and often too ashamed to discuss it with friends, colleagues, or even their spouses. This is, of course, heightened by their attorney's admonition, "Don't talk about this with anybody. Don't you dare share this with anybody." Here I am, a shrink, saying "Talk about it, this is important." Of course, that can be horrible for you outside of a clinical consulting room. I'm sure all of you know if you speak about it in any kind of therapeutic way, that information is privileged. If you speak about it in any kind of collegial way or supervisory way, that is not privileged. We have often gotten ourselves into an interesting dilemma. With the curbside consultation you're not sure whether it is colleague-to-colleague or a pseudo-professional consultation entangled with need for privileged communication. So, all I can do is encourage people to get those emotional needs met because it is quite a threat to our psyches. Interestingly enough, within the home we found that if issues were opened up with the spouse the physician felt a lot better. The physician feared that the response from their spouse would be a lack of appreciation for the depth of their anguish. Now, in our work with physicians' spouses we found an interesting contradiction because, while physicians often felt real supported by their spouses around issues related to malpractice, within the spouse there was a real sense of inadequacy that they weren't doing



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enough to help their suffering mate, and they were frustrated because they didn't know how to help the doctor more. Spouses generally felt rejected by the physician during times of malpractice suits and they were generally unaware of the presence of major psychiatric symptoms including suicidal ideation.

But of course solely to focus on malpractice litigation is really to miss the majority of the stress that we face in medical practice. There are so many emotionally powerful events that occur in our daily lives that are difficult to talk about as well. Bill is a 38 year old endocrinologist on the faculty of the medical school where he did his fellowship. He enjoyed a close relationship with his mentor, who was 60 and head of the service. When his mentor's diabetes began to worsen, he asked Bill to assume responsibility for his care. Well, Bill was honored at the request, but was ambivalent and felt he couldn't say 'no'. His mentor took verIy poor care of himself and Bill felt helpless and overwhelmed as he watched his mentor slowly die. Bill never talked with his wife, Karen, about his feelings other than to say that he was frustrated that his patient, his boss and mentor, didn't take better care of himself Bill grieved this loss alone for years. As he heard physicians in our small group in Crested Butte describe their experience in dealing with the psychological impacts of a tragedy that had occurred in their practice (it was an emergency physician who was talking about the impact of seeing one of his family friends come in from an automobile accident and not being able to revive the patient). Bill began to weep. He shared his experience for the first time with his wife and the group and felt that he received the understanding and support from her that he had never allowed himself to experience. Now Karen had always thought that Bill's experience was more impacting than he let on, but she felt she got subtle messages from him not to push it.

The same thing happened to me day before yesterday. I am working with a young, female executive who was gang raped at gunpoint and she has never told anybody about this event and yet she is trying to end her life and no one can figure out why. She was in my office talking about this stuff for the first time, and she was scared to death, unsure how to handle what she feels, or if she should allow herself to express what she feels. Yet not expressing what she feels is killing her, a dilemma I would venture that many of you could identify with. She's scared and I'm scared, but we proceed cautiously. At the end of the day I go home and it's clearly with me. My wife says, "So, how was your day?" I can't begin to conceptualize my day for her in a way that makes any kind of sense. We're walking our 18 month old son around the neighborhood and it's the day before I'm leaving to come here. It's very hard for me to do that but it is obvious to her that something is eating me. She knows I'm not there. These are the kinds of things that happen for all of us and how do we negotiate — not the known catastrophes of a malpractice suit — but the everyday catastrophes that we have to respond to as a result of the profession that we have chosen to dedicate our work lives to?

These are the kinds of interactions, the degrees of emotional availability and emotional support. The expectations in a marital relationship are often negotiated between couples nonverbally. These non-verbal negotiations evolve into an unwritten psychological contract. These unstated and subtle psychological contracts, or silent agreements about these issues and other issues are typically made indirectly, and they can exert a powerful influence on the marital relationship. You see, we physicians often prefer this mode of interacting because then strong feelings don't have to be spoken to and the accompanying sense of vulnerability can be avoided. Instead, we try to work things out with raised eyebrows, disapproving glances, and subtle forms of encouragement and reinforcement. The problem, of course, is that things really aren't worked out this way. They're simply avoided. It's one more example of the mind-reading that I talked about earlier.

To say that we physicians have a preference for the non-verbal mode of communication, like sexuality is, sadly, not to say that our lovemaking is incredibly passionate. Physicians are notorious for allowing little time for sex. One wife described it as follows: "He sits up in bed reading medical journals until the last possible moment. Then he'll say, 'Are you ready?' and he places the journal open on the bedside table. Then he turns out the light, does his business in silence, and two minutes later picks up the medical journal reading exactly where he'd left off, not caring at all about me. I haven't climaxed since our first child was born, seventeen years ago." I share this vignette with you because it illustrates how there can be a complete disconnection between emotional intimacy and sexual relations in the physician's life.

We physicians are well acquainted, as our families are, with the psychology of postponement. We are masters at delayed gratification. I remember real conscientiously when I decided to go to medical school. I was a junior in college and I sat down with my then fiancee and said, "Okay, I've got two years more of college, I've got four years in medical school, and the average residency is about four years. I'm looking at about ten years here before I'm really going to be able to have a systematic time when I can reevaluate things in my life and make a change in course." She was thrilled! No, I'm kidding. But you know, people who didn't go into medicine — they went into business — they weren't thinking like that. That kind of planning and delayed gratification was not a part of their strategy. It was immediate gratification, not delayed gratification, that was a part of their strategy. We have

all of these sources of external flame which are dutifully there that we use to justify our lack of availability to ourselves and our spouses. We tell ourselves and our spouses, "You know, honey, I'm in med school now. I'm in my third and fourth year of clerkships, and I'm at the hospital a hundred hours a week, but I tell you, I'm going to pick a residency program that is humane. I'm going to pick a call schedule that is light and I'm going to make sure that we get into a residency program that will get me the training I want but at lifestyle that we want." Right. So we all go to internship and we're working more than we were at any other time in our lives, and we tell ourselves and we tell our partners, "You know, honey, I'm a resident. I really have no control over my schedule here. I wouldn't wish this on me, I wouldn't wish this on you and I tell you, as soon as I'm done with my residency I'm going to set up a practice where, dang it, we're going to have time together." And we believe it and they believe it because we believe it. Then we finish our residnecy program and we join a group. We're $100,000 in debt, we need to make some money, so we join a group. Of course, we're not home at five o'clock. In fact, we are the ones who are expected to build our practice, see the late consults, spend time in the doctor's lounge, and we tell ourselves and we tell our wives, "Honey, this only temporary. You just wait until I make senior partner, then I'm going to slow down. Then we'll have some time together." But of course, the wife may finally realize that the psychology of postponement may in fact be the psychology of avoidance. She may get fed up and decide to leave.

In the traditional marriage, the physician's wife realizes that she has been waiting for so long for her husband to change that she has developed no identity for herself other than that of being a doctor's wife. While her husband may be feeling that he has established himself a little bit and can now enjoy the domestic life that he has been depriving himself of all these years, his wife has become stir crazy and has decided to leave and wants an identity separate from that of her husband's. The process can lead to a crucial cross-over in mid-life. Just as he turns to her for more intimacy, she is on her way out the door. "But why leave now? I've been impossible for years!"

I'd like now to turn my attention to women physicians' marriages. Although there are some important differences in male/female psychology, many female physicians are just as compulsive as their male counterparts. The principal difference is that women tend to value emotional relationships throughout their lives better than male physicians do, and as a result female doctors do somewhat better with emotional intimacy than men. For female doctors, division of labor was a major source of conflict. Seventy-five to eighty percent do their own housework and cooking. Most female doctors grew up in non-medical homes. Most female doctors grew up in traditional homes and feel guilty about their lack of domesticity. They make up for it by trying to be superwoman. On top of all their work responsibilities, child care responsibilities, and home responsibilities, this leaves little time for their interaction with their spouses. Here's supermom cooking with a toddler tugging at her dress, a baby in the high-chair, a mess everywhere, and her husband smoking his pipe saying, "I don't understand you, Helen, you used to be such a fun person."

Married women doctors often complain that they fall asleep in the evening over journals, books and papers while their physician-husbands seem to have renewed energy. Now one reflection of several stereotypes in our culture is that we men are congratulated for helping out around the house as if we are just truly magnanimous for doing so. If I'm spending time with my son and one of my male friends calls me up he says, "Oh, are you baby-sitting today?" Now if one of my wife's friends calls her up they don't say, "Oh, are you baby-sitting today?" My point is that women are simply expected to do the housework and to do the child-care work and are implicitly or explicitly criticized if they try to avoid it. "Why don't you get the kids dressed and I'll go outside and honk the horn?"

Responsibility for child-care nearly always falls on women as well. If a child is sick, the wife is expected to take the time off work to care for the child. If cookies have to baked for school, if there is a teacher's conference that needs to be attended, if someone has to be home when the refrigerator arrives, it's usually the wife who is expected to take care of such responsibilities. Men may cooperate with sharing these duties, but also often secredy resent it.

Another major source of conflicts is that wives of male physicians usually felt much more comfortable being a support for their husband's careers. Males who are married to female doctors felt much less comfortable being a support of their wives' careers and felt that this is often a much more onerous obligation. As middle age arrives, female doctors are likely to experience even greater strains placed upon their role as nurturer. You know, typically women assume responsibility for the care of elderly parents or in-laws, while men are not as much expected to serve in these capacities. At the same time, the female physician is dealing with the loss of her children growing up and leaving home, she may be also dealing with the loss of aging parents. After nurturing others all day at the office, returning home to nurture children and aging parents, the female doctor often wonders, "Who nurtures me?"

Husbands of female physicians experience a number of unmet needs. One psychiatrist who treated in psychotherapy a number of husbands of female physicians found a recurring set of complaints. I'd like to let you know that this data that I'm about to present is different than the data that I've presented thus far

because the data that I've talked about thus far has come from surveys and questionnaires from workshops and other scientific studies. The data that I'm about to present to you has come from one fellow's clinical practice, so these are people that went to him because they had problems.

First, they felt unimportant to their wives. They felt that they were low on the list of their wives' priorities. They felt un-nunured and in need of attention and care. They did not feel affirmed as men. They harbored considerable resentment towards their wives' patients, and they all longed for a greater degree of intimacy—emotional and sexual. One important aspect of this study is that these needs were not necessarily conscious until after psychotherapy had begun. These were not guys who went into the psychotherapist's office and said, "You know, doc, I don't feel affirmed as a man. I am un-nurtured and in need of attention and care." These are needs that became apparent only after a considerable amount of work in psychotherapy. They were often completely unable to express these feelings to their wives, and over half of them have been involved in extra-marital sexual affairs.

Before closing, I'd like to turn my attention to some preventive measures. First: Define and clarify the problem. Be sure you know what it is you want to change. As you all know, the cure can be worse than the disease. You know, we all need our miseries and complaints. One wife in our workshop, in our small group, rejected every bit of advice. She came with an unsolvable dilemma and even though the group was trying like heck to solve it for her, which is a problem in and of itself, she rejected every bit of advice until one of the other group members said, "You know, you're kind of a 'yes, but' person. Everything someone says to you, you find a way to defeat it. It's like someone playing badminton — you just kind of bat it away." At that moment, the person realized that in fact she was being a 'yes, but' person and that she had some emotional investment in the suffering and that this was quite important to her. **Second:** I think the most important ingredient is to realize that no solution is going to be perfect, and this can be difficult for perfectionists. It's just impossible to balance work and family life in a way that pleases everybody all the time. A key ingredient is to lower your expectations. **Third:** Make time to talk, even if it is only fifteen or thirty minutes a day. Those couples that talk more need marital therapy less. Sometimes more than talk is needed. Some of us need to learn, or relearn, how to talk. This is a frequent request at our workshops. Make things explicit. Don't rely on mind-reading. One physician in our group sulked hoping that his wife would give him a backrub and he said, "You know, if I have to ask for it, it's really not worth getting." Do something together. No one knows what love is exactly. James Thurber said, "Love is what you've been through with somebody." Of course, his point is that companionship is much easier to define than love. Carve out some time for the two of you away from the kids to pursue a common interest, and don't feel guilty about taking time for yourselves. **Fourth:** In the traditional marriage it is important for the woman to establish her own identity separate from that of her spouse. In the two-professional marriage, there needs to be a clear and explicit discussion and negotiation about shared responsibilities for home and children. **Fifth:** Make time for a sexual relationship. If there is no time for sex, it's symptomatic of more basic problems. The avoidance of sexuality must be discussed before it becomes chronic. An element of surprise, of unpredictability, can go a long way to liven up a sexual relationship. Here's the same guy in the overstuffed leather chair and the wife in a slip walks in. Quick!—what is your gut reaction? I can't stress enough the importance of compromise. There's just no magic in any of this. People often go to marital therapy hoping that the therapist will change the spouse, but not them. Each side must be willing to give and take and compromise. "I will abandon my medium and shorter range missiles if you'll abandon yours."

I'd like to close by restating some of these thoughts in a broader context and quote the philosopher, Reinhold Niebuhr, in his 1952 book entitled *The Irony of American History*: "Nothing that is worth doing can be achieved in our lifetime, therefore, we must be saved by hope; nothing which is true, or beautiful, or good makes complete sense in any immediate context of history, therefore, we must be saved by faith; nothing we do, however virtuous, can be accomplished alone, therefore, we must be saved by love."

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Needs: Full-time

Jackson County Hospital
Scottsboro, Alabama
170 Bed Facility
Annual ED Visits: 17,000
Needs: Full-time, part-time

Russell Hospital
Alexander City, Alabama
100 Bed Facility
Annual ED Visits: 13,000
Needs: Part-time

Mississippi

Parkview Regional Med. Center
Vicksburg, Mississippi
231 Bed Facility
Annual ED Visits: 15,000
Needs: Director, part-time

Montfort Jones Memorial Hospital
Kosciusko, Mississippi
76 Bed Facility
Annual ED Visits: 8,000
Needs: Full-time

BMH - Union County Hospital
New Albany, Mississippi
153 Bed Facility
Annual ED Visits: 18,000
Needs: Full-time

BMH - North Mississippi
Oxford, Mississippi
150 Bed Facility
Annual ED Visits: 15,000
Needs: Full-time

Gilmore Memorial Hospital
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At Home

by Robert Lokey, M.D., FACP

The announcement sits open before me of the upcoming Annual Alumni Weekend. It so happens mine is one the Graduating classes scheduled to reunion - the class of 1955.

Forty years ago. What an assortment we were. Eighty students, four women, the first class to enter so many – a group of such diverse age and experience as to make the head swim: survivors of the Italian campaign, the Battle of the Bulge, air and sea engagements, along with those right off the farm, out of countless small towns and some who'd struggled a year or two through graduate school. We eyed each other warily.

The junior and intermediate faculty delighted in reminding us how few would probably reach graduation. That malicious practice stimulated us to seek out "buddies" we could depend on for survival and constantly scan all the others for signs of sabotage. A wonderful milieu in which to learn the required things necessary to become that which society honored and treasured: "the doctor." Amazingly, we graduated eighty – two joined us enroute and filled the vacancy of two who dropped out.

Twice a decade since the early 1970's we've gathered to reacquaint ourselves and the old interfaces have softened.

But why convene? Few have stayed in close contact with each other over this long period. As a testimonial to survival? Perhaps – but look then at the site of the convention. It is even more a stranger.

Monolithic structures of eclectic architectural design crowd an area once familiar to us. To step forth into the area is like being a pigmy trapped amongst all the inhabitants of Jurassic Park herded into a tight corral. Sunlight at midday has to struggle to reach the surface intersect of Seventh and Nineteenth! Embrazen yourself to look up an old Faculty friend or acquaintance and you're confronted with a search comparable to finding the entrance into a pyramid.

Suppose your luck holds and you gain entrance to the labrynths beyond the foyers – you encounter droves of the white-coateds, who scan you instantly with the calm of a gun-slinger and the reliability of high-proton probes: "not - a - competitor" is immediately read and your presence is dismissed.

Marquees and Bulletin Boards are creatively misdirectional and all but the most determined likely gives up. Functional Security there.

I recently made such a failed search. My friend, a distinguished professor nationally honored for his teaching, was no longer there. Only later did I learn he had become "too senior" for the Center to sustain him – traditional relationships could not hold, things fell apart; I'm uncertain they were replaced with something of value.

I shake my head free of these thoughts and look again at the announced program. A "new" feature: "MEDICAL SCHOOL OPEN HOUSE", a chance to hear an address on "The State of The Medical School" by the relatively new dean, an academic with an impeccable array of credentials and a discussion by an executive on "new managed care planning." Hmmmm – the new morality and competition.

I'm going to skip this gathering. They're all good people, I'm sure, but we're strangers to each other and they have no interest in my survival – not that which makes it possible but that which makes it worthwhile, as Will Percy put it in talking of values and gallantry.

In one of his novels Wallace Stegner had a character say recollection is about one-half invention. I think I'll stay home and "invent" some buddies.

THE SOUTH AND NORTH POLES

At least one Alabama physician has "stood on the ice" at the South Pole (ice one mile thick) (fig. 1), and at the North Pole (ice twelve feet thick). He is Alston Callahan, M.D., who when he discontinued examining and operating on eye patients in 1990, switched over to increase the development of retinal research at the Eye Foundation Hospital. "Getting to the South Pole is more uncertain and hazardous than reaching the North Pole," said Dr. Callahan. "This is because access to it is limited to walking, skiing, or by aircraft, and few have the stamina or knowledge to cross Antarctica by surface. This is especially true since dog teams are no longer permitted in Antarctica. All flying schedules contain the phrase 'Weather Permitting'."

To begin celebrating his 84th birthday, Dr. Callahan flew on commercial flights to Puntas Arenas, a city of 150,000 on the Straits of Magellan near the tip of South America. The hole of the ozone layer extends over this city, and its inhabitants are careful to wear sunglasses and sun block protection on their faces and hands. Only in the southern summer (late December, January, and early February), is it possible for private individuals to visit the Pole. Dr. Callahan and nine other adventurers were flown over the Drake Passage between South America and the Antarctica Peninsula in a four engine turbo-prop Hercules plane, an enormous aircraft which carries mostly freight and only fifteen to twenty passengers. Their flight continued across the length of the Antarctic Peninsula to the base camp, located at a mountain range named Patriot Hills, a distance of about 3,000 miles. This site, discovered about seven years ago, is the first bare ice runway to be located and developed in the continent. This natural phenomenon of nature is the most southerly landing strip in the world. All other aircraft landings in Antarctica are made on ski-equipped aircraft.



Figure 1 – The flags in a semi-circle around the South Pole represent the countries who signed the Antarctic Treaty. In the background to the left is the geodesic dome of the United States Amundsen-Scott Weather Station. On January 9, 1995, when Dr. Callahan was there, the temperature was 30° below zero; the wind was moderate.

At Patriot Hills, the adventurers lived in small canvas tents, two or three persons in each (fig. 2). In January, when the sun was obscured by clouds, the temperature ranged from 0° C. to -15 C. The tents

were heated only by the sun, which is overhead twenty-four hours a day. For clothing, a woolen jacket and pants were pulled on over "long johns," and on top a special parka and trousers filled with down feathers were worn. At "night," specially designed sleeping bags were used. Food was plentiful, prepared by the staff, cooked on an oil stove and served frontier style - brunch at 10:00 a.m. and dinner at 7:00 p.m. Toilet facilities were in igloos constructed of blocks of ice.



Figure 2 – Base camp at Patriot Hills mountains, the site of a natural, flat, bare ice runway, where wheeled aircraft, as a Hercules cargo plane can land. The adventurers live two to three in a tent, heated only by the sun, which circles overhead around the clock in summertime.

Onward travel to the Pole is by a Twin Otter plane (figure 3), designed for use only in the Arctic and Antarctic regions. They have two motors, two pilots, one of whom is the navigator and the other a radio operator, an additional inboard fuel tank, are ski-equipped, and will seat a maximum of ten passengers.

The South Pole is in the center of the continent of Antarctica, which is the size of the United States and Mexico combined, at 9,300 feet above sea level. For three days, the group checked on the weather reports frequently. Finally, on the fourth day, clear skies were reported and off they went. After enjoying the excitement of actually standing there and taking photographs, they were given a brief tour through part of the United States Amundsen-Scott Weather Station, about three hundred yards from the Pole. Station officials have no



Figure 3 – After waiting in the tents for three days, on the fourth, the weather permitted the Twin Otter to fly, in four hours, the remaining 650 miles to the South Pole.



Figure 4 – The Russian icebreaker, the Yamal, has 75,000 horse power from thermonuclear reactors. From the port of Murmansk, it crosses the Arctic Ocean directly through the ice sheet to reach the Pole in six to seven days. After a few hours there, it returns on to Murmansk, or it goes on across the top of the world to Providenya in Siberian Russia, which is across the Bering Strait from Alaska.

enthusiasm for welcoming visitors, but are reservedly courteous during the brief walk-through. Neither coffee, nor tea is offered, and no souvenir purchasing is available.

The group remained at the Pole no longer than three hours, for cloudy weather was closing in and the pilots were nervous, fearing inability to take off. About half-way back to the base camp, a stop was made at a fuel cache to take on more fuel. At Patriot Hills, there was another wait for two days until the weather permitted the Hercules plane to be flown from Puntas Arenas to take the group back. From that point on, travel was by commercial airlines.

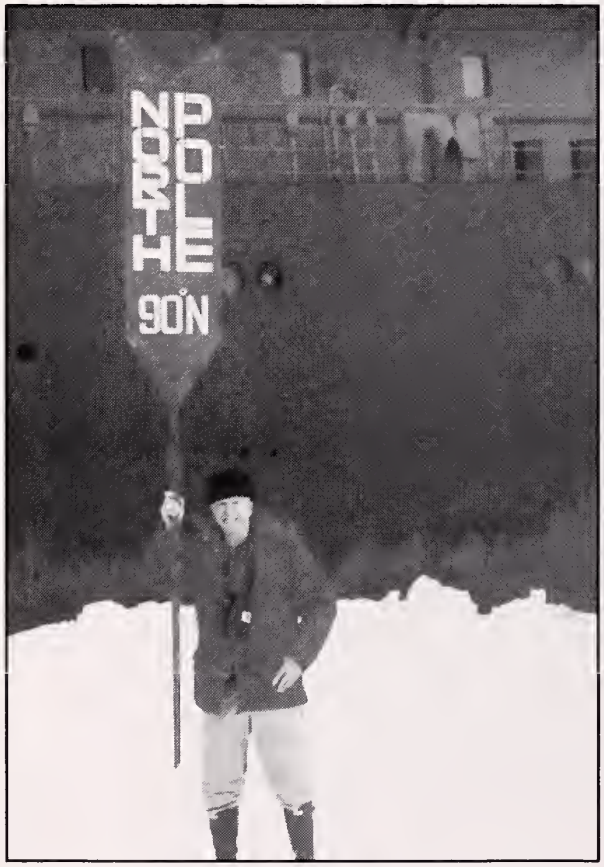


Figure 5 –August 30, 1993. Ice twelve feet thick, temperature 0º Centigrade, no wind. Time infinite, at 90º north.

Comparison with a journey to the North Pole? "All you have to do to get to the North Pole is to fly to Helsinki, Finland, then a chartered flight via St. Petersburg to Murmansk, climb aboard a comfortable nuclear powered Russian icebreaker (fig. 4), and be driven straight to the Pole," replied Dr. Callahan. "The Arctic Ocean covers the top of the world, and the ice at the North Pole is about twelve feet thick. The icebreaker plows through it to the Pole and anchors. Then the passengers walk down the ship's ladder, get out on the ice and hold on to the pole (fig. 5). Reindeer barbecue and champagne are served. They dance around the pole, and when their feet get cold, they walk back up the ship's ladder to their warm cabins."

Dr. Callahan's travel exploits began on his 80th birthday when he swam across the Yazoo River (temperature 55- F.) at his hometown of Vicksburg, Mississippi. During his eighth decade, he has so far journeyed to Tombouctou in Western Africa, Palitania in Western India, and Easter Island in the South Pacific.

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Manuscripts from member physicians should be typewritten, double spaced on white paper 1-1/2 x 11 inches with adequate margins. Two copies should be submitted. Authority for approval of all contributions rests with the Editor. *Alabama Medicine* reserves the right to edit any material submitted. The publishers accept no responsibility for opinions expressed by contributors.

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The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

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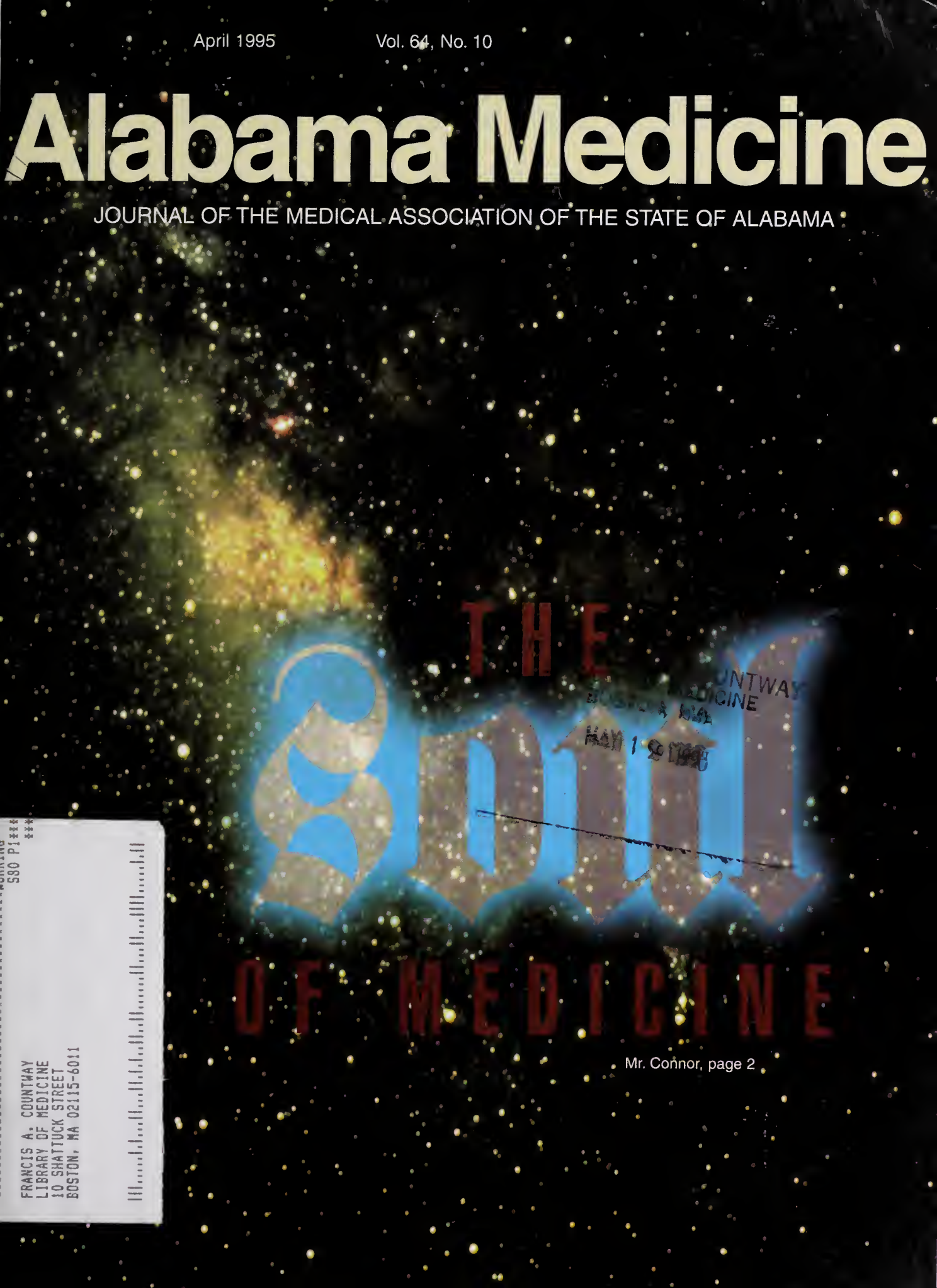
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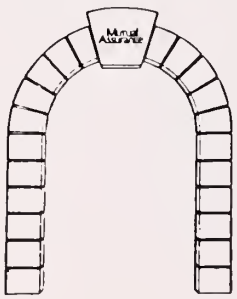
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S. Lon Conner
Executive Director, MASA

The Soul of Medicine

Medieval philosophers and theologians debated at great length over the site of the soul in the human body. If memory serves, some argued that the soul resided in the liver, others in the heart or the brain, with minority views locating it in on near various other organs.

Most of the world's religions, whether they subscribe to a palpable soul or not, embrace its existence as central to the faith.

Dr. Faust of German legend – immortalized by major dramatists, including Marlowe and Goethe – cut a deal with Mephistopheles for 24 years of power and magic, at the end of which time Faust's soul would belong to the devil.

Thus do we speak today of a "Faustian bargain," or contract, by which is meant the vainglorious act of someone who sells his soul to the forces of darkness in return for transient earthly pleasure or privilege.

In this strange period of American medicine, some doctors believe that too many of their peers have cut Faustian deals with HMOs and other commercial entities, now seen as collectivizing medicine at least as aggressively as projected in Ira Magaziner's infamous blueprint of 1994.

Whatever truth there may be in that contention, there is mounting concern among thoughtful physicians that the profession is locked in mortal combat with commercial predators over the soul of medicine.

But many of these same physicians seem to doubt that the professional peril is exclusively external. They hold to the view that doctors are themselves accountable for any decay of the professional soul or *ethos*. In this view, the intrusions of third parties do not relieve or excuse physicians of their absolute obligations to their patients and to the fundamental doctrine of their profession.

These sentiments seem particularly strong in the line of MASA presidents under whom I have been privileged to work. Arguably, that is the reason they wanted to serve in this capacity. Looking back to the genesis of MASA in the last century, it seems more than probable that most of the presidents since the 1870s have devoted a major portion of their time and talent to serving as the conscience of their profession. And that tradition has continued to the present.

For example, consider the writings in *Alabama Medicine* of the 1994-95 President, Garland C. Hall, M.D., whose term ends this month; and the known views of his successor, C. Neal Canup, M.D., whose profile will appear in the May issue of *Alabama Medicine*.

The soul of medicine, although not stated in those terms, has been the primary theme of Dr. Hall for the past year and I expect it to be a major focus of Dr. Canup in the year ahead.

As I read both of these leaders, they embrace the classic ethical principle that the medical profession has been and must always be guided by what ethical philosophers call *summum bonum*, the highest good, a value system of conduct and thought that is desirable and obligatory in itself, not merely as means to an end.

This, they both believe, is the essence of the profession of medicine, and both fear that because of what has been aptly termed the monetarization of medical care this essence may erode through neglect.

Their shared belief is that this possibility poses the greatest threat of all to their profession – catastrophic and conceivably irreversible damage that all the third parties in the universe could not inflict.

It may be more than coincidence that Drs. Hall and Canup are both the product of small southern towns: Dr. Hall was born in Goshen, Pike County, South Alabama; Dr. Canup in a small sawmill community of White County in the Blue Ridge Mountains of Northeast Georgia.

Is there something about small town beginnings that seems to initiate a life of reflection and contemplation? I don't know whether or not there is empirical evidence to support the thesis, but it has been my observation over the years that the lifelong search for the simplicity of fundamental truths is often strongest in those whose early years were uncomplicated by metropolitan commotion and stress. (And I say that as a city boy.)

In any case, MASA physicians are well served by Presidents who are concerned above all else with the fundamental value system of their profession. If I were formulating a job description for the office, I believe I would place this duty No. 1.

Their job in this regard is not made any easier by the times in which we live, times where the dog-eat-dog philosophy espoused by the German philosopher Friedrich Nietzsche (1844-1900) has taken root in the land of the free.

Totally rejecting centuries of Judeo-Christian teaching as a "slave ethic," Nietzsche scoffed at soft-headed Western notions of moral law. He built his own warped concepts of ruthless and unremitting struggle as the basic law of nature on corrupt misinterpretations of Darwinian evolution.

Not only was Nietzsche to become the patron saint of 20th century fascism, his philosophy has been enthusiastically embraced by predators today, those in our society who argue, with Howard Millken and his ilk, that "greed is good" and exploitation of people a worthy pursuit.

(Contrast this abomination with the famous "categorical imperative" of an earlier German philosopher, Immanuel Kant [1724-1804]. Kant's imperative systematized the Judea-Christian Golden Rule thus: "Act as if the principle on which your action is based were to become by your will a universal law of nature." No one has stated the case for the basis of moral law any more concisely. Nor has anyone laid down a better short definition of medical ethics.)

Plainly, some of the money mad opportunists now invading and traducing the health care system totally reject Kant and adore Nietzsche. The physician's centuries-old professional tradition is thus violated and called into question by the guiding philosophy of the rampant profiteering they see all about them in a dollar driven industry.

Fearing physicians themselves will be infected by this deadly virus, or will simply throw up their hands in desperate surrender, Drs. Hall and Canup wisely see the MASA presidency as a pulpit for rededicating their peers to the old-time religion of medicine.

And that credo mandates the hard but necessary doctrine of selfless devotion to the soul of medicine, now being tested as perhaps never before in this country.

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PRESIDENT'S PAGE



Garland C. Hall, M.D.
President, MASA

Hail and Farewell

When I assumed the office of President of MASA a year ago, I expected that the ensuing 12 months would provide all manner of fresh insights into health care in general and our profession in particular. For one thing, I had counted on the reform debate to lead me to a deeper understanding of the micro and macro economics of health care delivery.

Instead, the great fiasco produced little more than the superficial rhetoric for which Congress is famous – or infamous. All heat, little light. The *quantity* of the debate was signicantly greater than normal but the *quality* merely confirmed my belief that Washington is basically dysfunctional.

Therefore, I am constrained to report that, in spite of my sincere meditations and earnest invocations to the gods of enlightenment, my views remain pretty much unchanged – as they have since I entered practice June 26, 1963.

Essentially those views are that:

- whatever parallel universe of health care is constructed by the public and private sectors, our profession remains the most rewarding of all human endeavor;
- whatever transpires in that universe of virtual unreality that assorted pundits, the press and politicians have fantasized, unstinting patient care should receive about 99% of our thought and concern, as both our duty and our high privilege;
- and, finally, that the more things change the more they are the same.

It is the latter point to which I will address most of this, my final message as President, in the belief that a brief review of the past should suffice to illustrate the point that today's certainty is tomorrow's doubt, just as today's doubt may be tomorrow's certainty.

Consider, first, the following quotation by a prominent Washington figure:

"For growing numbers of Americans, the cost of care is becoming prohibitive. Even those who can afford most care may find themselves impoverished by a catastrophic medical expenditure. The quality of medicine varies widely with geography and income. Because we pay so little attention to preventing disease and treating it early, too many people get sick and need extensive treatment. We are investing more of our nation's resources in the health of our people, but we are not getting a full return on our investment....

"For many of our families, the anguish of a serious illness is thus compounded by acute financial anxiety. Even the joy of recovery can often be clouded by the threat of bankruptcy...

"I am proposing that [an] Act be adopted which will require employers to provide basic health insurance for their employees. ln the past we have taken similar actions to assure workers a minimum wage, to provide them with disability and retirement benefits and to set occupational health and safety standards. Now we must go one step further and guarantee that all workers will receive adequate health insurance protection...

"I am also proposing that a new... plan be established to meet the special needs of poor families. Medicaid suffers from defects that now plague our failing welfare system. It largely excludes the working poor...

"Nineteen months ago I said that America's medical system faced a massive debt *crisis*. Since that statement was made, the crisis has deepened. All of us must now join together in a common effort to meet this crisis – each doing his own part to mobilize more effectively the enormous potential of our health care system."

Was that Bill or Hillary Clinton? Ira Magaziner? One of 1994's reform advocates in the House or Senate? If you guessed any of these, you're off in both time and political philosophy. That was President Richard Nixon, addressing Congress Feb. 18, 1971 – twenty four years ago.

The "crisis" of a quarter century ago is still, they say, a crisis. At least President Clinton confirmed the warnings of President Nixon and the new Republican Congress has only changed the spin on the same claim.

The more things change, the more they are the same. Crises come and go and so do their opposite – rosy predictions for the future.

Go back 50 years to 1945. Sir Alexander Fleming shared the 1945 Nobel Prize in physiology or medicine with the British scientists Howard Walter Florey and Ernst Boris Chain for their contributions to the development of penicillin, which Fleming had discovered in 1928. I need scarcely tell you that contemporary press accounts, fueled by expert opinion of the day, informed the public that infectious diseases would very soon be a thing of the past in the world, totally eradicated by antibiotics. And I need scarcely add that this forecast has not proven precisely accurate.

In that same year, the atomic age was born at Alamogordo, New Mexico, on July 16, and was to demonstrate its terrible potential at Hiroshima and Nagasaki three weeks later. In the aftermath of the Japanese surrender, the world was reassured that The Bomb would prevent all future wars, and that cheap atomic power would make the deserts bloom, eradicate all hunger and disease, and generate enduring, worldwide prosperity for all mankind.

I think you will agree that this forecast has proven a trifle too optimistic.

Go back 100 years to 1895. Our professional forebears were still struggling in that year to create a public health system in Alabama as well as to establish higher standards of medical practice. In 1895 Cubans were fighting to free themselves from Spain and assure their liberty from tyranny for all time. The third volume of Karl Marx's *Das Kapital* was published (posthumously), predicting the ultimate defeat of capitalism, supplanted by a worldwide socialist paradise. Millions believed it and continued to believe it until the last decades of the following century.

Not all prophecies of 1895 proved false, of course. In November of that year, Wilhelm Conrad Roentgen read before the Physico Medical Society of Wurzburg, Germany, his discovery of short-wave radiations he called x rays. True to a few daring predictions, it was to revolutionize medicine and physics.

Similarly, Marconi's invention of radiotelegraphy in 1895 did shrink the world, as some predicted. And the death that year of Louis Pasteur underscored the belief that medicine had indeed entered the scientific age.

That was also the year that King C. Gillette invented the safety razor and it turned out pretty well. Still, other predictions proved false: the press of the day said nobody would ever be interested in professional football after the first pro game was played in 1895 at Latrobe, Pennsylvania.

My point being that prophecies, straight line projections and forecasts of either salvation or doom, while occasionally accurate, have proven notoriously unreliable. Yet the proponents of health care reform, this year as well as last, support their claim of critical urgency for drastic surgery by resorting to just such forecasts.

Trends, fads, popular movements, public alarm, political revolutions, futuristic visions, and the rest, come and go. But the phenomenal progress of medicine in the second half of this century, revolutionary as it has been, has not altered one whit the fundamental vitality and sanctity of the doctor/patient relationship. It has survived centuries of wars, plagues, dictatorships and and persistent attempts by bureaucrats, greedy merchants and tyrants alike to kill it.

Yet it endures as the one fixed point in a madly confusing world. It will never die because with it would go the one enduring example of man's humanity to man, the central promise of Judeo-Christian Western Civilization.

If you believe that, as I do, you will maintain your serene confidence in your science and art whatever the public and private sectors may throw at us. They can destroy the central covenant of medicine only if we let them – through either weakness, failure of resolve, or active collaboration with the forces targeting the doctor-patient sanctuary.

I thank you for the high honor of serving as your steward for the past year. Keep the faith.

A Case of Lumbar Hernia Occurring Through Surgical Defect of Iliac Crest

by David E. Lipton, M.D.
T. Nagendran, M.D.

Hernias occurring in the lumbar area are rare. The lumbar area is a broad anatomic area bordered superiorly by the 12th rib, interiorly by iliac crest, medially by the erector spinae muscle and laterally by the external oblique muscle[1].

Acquired hernias occurring in the lumbar area are often diffuse and grotesque appearing and most of them are post operative incisional hernias occurring in nephrectomy incisions. Rarely hernias occur through bicortical surgical defect of iliac crest. We would like to present such a case and review the literature briefly.

CASE REPORT:

A 45-year-old female presented with a painful growing mass in the right lumbar area and upper gluteal area in August of 1991. Eight years prior to this, she had undergone a spinal fusion, following two unsuccessful laminectrosies (fig. 1).



Fig. 1: Pre Op X-Ray. Please note intact ileum

The bone graft for spinal fusion was harvested from the right iliac crest (fig. 2). The post operative period was complicated by wound infection and dehiscence of donor site which contributed to development of incisional hernia.



Fig. 2: Defect in the right iliac crest

Department of Surgery, VAMC Montgomery.

After two months of unsuccessful conservative management, patient was operated upon. A preoperative barium enema (fig. 3) revealed the cecum and ascending colon as the contents of hernia.

During surgery, the hernia was reduced and repaired by a double layer of marlex mesh, one layer medial to the ilium and the second layer lateral to the bone. Holes were drilled in the bone and the mesh was anchored around the defect with proline sutures. Patient is 3 years postop now and is extremely happy with the results and is symptom free.

The ilium is a frequent source when a bone graft is required. With the patient prone, the posterior one-third of ileum is available to the operating surgeon. In most cases a unicortical graft provides the orthopedic surgeon with adequate stability and osteogenesis that a procedure demands. On occasion however, a bicortical graft is deliberately or in-advertently taken. In such cases a significant osseous defect may result, predisposing such patients to hernia formation.



Fig. 3: BE showing Lumbar Hernia

Such herniation is rare. A more common defect in the immediate anatomic region that is encountered by the general surgeon, is a hernia occurring through the inferior lumbar triangle. This is better known as Petit's hernia and occurs through the area bounded anteriorly by the posterior border of the external oblique, posteriorly by the anterior border of the latissimus dorsi muscle and interiorly by the iliac crest.

Petit first described the boundaries of the inferior lumbar triangle in 1783, and related his experience with a strangulated hernia through this area. 77% of adults have this space[1]. Women with a wide pelvis displace the external oblique anteriorly and latissimus dorsi more medially creating a wider base to the triangle.

The orthopedic surgeon should carefully check for this weakness in any patient from whom he plans removing bone in this area. In addition to the routine examination of the back, the surgeon contemplating taking an iliac graft for whatever purpose is cautioned to use a unicortical graft whenever possible. If bicortical bone graft is obtained, then careful approximation of periosteum and muscular origins with interrupted sutures will prevent future herniation.

CONCLUSION

A rare case of herniation through bicortical bone defect of iliac crest is presented.

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The Real Contract With America

*Ronald E. Henderson, M.D.**

We have all heard a lot about the Contract with America in the last six months. Certainly, the Contract with America is representative of a new spirit in our national government and in our nation. Unfortunately, the Contract I'm referring to does not include provisions for meaningful health care reform.

As a physician, I'm very concerned about getting our nation's health care system on the right track. It is the best health care system in the world and we need to ensure that it remains so.

One of the elements that has made America great and the envy of the world is its ability to provide first rate health care for all of its citizens. Right now, that capability is being threatened by a system that allows runaway costs and colossal inefficiencies.

Doctors and patients alike need to understand that this old system is what drove medical costs — and in the end — patient costs, out of sight.

Contrary to popular belief, "managed health care delivery" is not a euphemism for care that is inefficient, non-personal, and costly. Rather, it's a system that is replacing the out-of-control fee-for-service system.

So whether you're ready for health care reform or not, here's what to expect:

1) Physicians Will Affiliate – Small, private group networks, large corporate networks, and hospital physician networks are here to stay. They increase economies of scale, increase cost and expense efficiency, and increase the overall amount of bargaining between physicians, providers, hospitals and other entities.

As in any industry, the effects of this increased efficiency and stiffer competition for business will benefit patients through lower costs and more effective treatment and service.

2) Managed Care Is Here to Stay – Organizations providing "managed care" are rapidly replacing our traditional "health insurance" carriers. The increasingly popular HMO and other managed systems are taking home report cards that are equal to or better than the fee-for-service systems.

Nationally, HMO enrollments have exploded from 40 million subscribers in 1992 to almost 55 million today. One in six people are covered by HMOs and enrollment has doubled since 1986. There is no end in sight, and our part of the country won't escape the boom.

3) A Reduced Number of Medical Specialists – Many health care consumers find this difficult to digest, somehow feeling that the caliber of care will be affected. But it's simply the law of supply and demand.

First of all, new medical technology, a healthier patient population, and advances in pharmacology have diminished the need for specialists. Even the American Medical Association has reported that there will be a surplus of 165,000 specialists by the year 2000.

In addition, the continued acceptance of "gatekeepers," better known as primary care physicians, that are assuming responsibility for a patient's overall health and treatment further reduces the need for as many specialists.

4) Health Delivery is Moving to an Ambulatory-Based System From a Hospital-Based System – This reinforces the "gatekeeper" concept and the notion that the primary care giver should assume the responsibility for a patient's overall health and wellness. And whenever possible, that means maintaining and treating patients outside of the hospital.

The vast majority of physical problems, illnesses and injuries can be treated in a doctor's office or clinic. Hospitalization should be considered only when it is absolutely necessary. The sooner physicians and patients can come to terms with this reality, the faster our health care costs will come down. Hospitals and comprehensive medical centers will still play a vital role in treatment and research, but they will not be as prominent as in the past.

5) Medical Practices Will Become More Flexible – Successful practices will be flexible and creative in setting fees, scheduling office hours, participating in various health care plans, working with employers and seeking new and better ways to treat and manage patients. This includes more marketing and invitations to the consumer to compare services and personnel.

Patients and employers will be attracted to physicians and facilities which combine their resources and capabilities with those of other practices to better meet their needs.

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6) Practice Guidelines Will Create Higher Standards of Treatment – More and more, individual practices and medical staffs will follow established protocols, or "practice guidelines." These guidelines will reduce the damage of malpractice claims, allow better tracking of outcomes, and eliminate much of the defensive medicine that is now being practiced. Patients will realize a greater consistency of care and will feel more comfortable with treatment decisions and processes.

7) Preventive Medicine Will Become a Way of Life – Health care providers are moving from a treatment-of-illness orientation to the management and maintenance of health and well-being. The health care delivery system of the past placed little value on preventive measures or wellness, but this is changing rapidly.

Because its effectiveness has been proven, employers are now willing to pay for the real value of preventive medicine and wellness programs.

8) More Attention Will Be Focused on Patient Satisfaction – Although most physicians have focused on patient satisfaction throughout their careers, it has never been quantitatively measured. With the advanced technology of today and the increasing importance of "customer satisfaction" in every other industry, that is no reason why health care cannot be measured, in part, by the satisfaction levels of those it treats and selves. Patients want and need to know how other patients rate a particular practice or physician, and doctors and physician networks want and need to know how to improve their services.

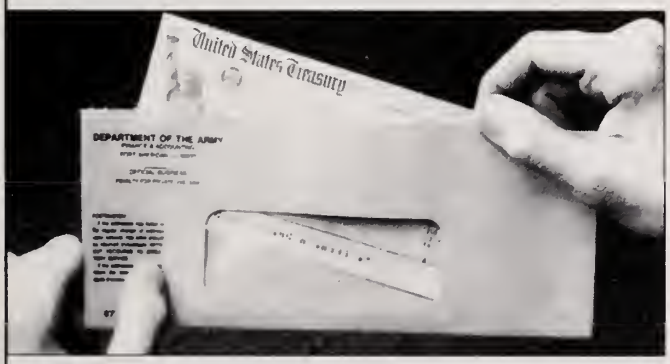
It isn't difficult to envision the day when the claim of highest patient satisfaction level will be more enviable and valuable than any other satification, award, or recognition a health care facility or professional can earn. Health care consumers have much to look forward to in terms of better service.

9) Health Care Partnerships Will Flourish – Cooperation is absolutely essential in the health care system of the future. The vast array of disciplines and functions in our current system will become more integrated, and partnerships with physicians, other health care professionals, employers, insurers, hospitals, HMOs, and other public and private institutions will become commonplace. Eventually, the system will be incredibly streamlined and "user friendly" for the patient and practitioner.

10) Medical Outcomes Will be Measured and Evaluated – The only way to establish how well our

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health care system is working and if we're getting our money's worth is to have comparative information. The procedures performed, the medications prescribed and the eventual outcome, or resolution, of the physical problem must be evaluated against the cost.

This type of information gathering and "number crunching" will allow us to identify successful treatment patterns and important trends. By reporting successes and failures, physicians will be able to review the treatments of thousands of patients to see what is most successful. Consumers and insurers will benefit from the improved treatments and inevitable cost-savings.

The rate of change in health care consolidation in this country – particularly the Southeast – far exceeds anything we expected. The window of opportunity to integrate health delivery systems, however, is likely to be limited. The health care industry needs to move quickly, and the consumer will play a huge role in driving these changes.

It's a matter of survival for many physicians and hospitals. The profession and its consumers should look beyond mere survival and anticipate changes which will lead to a system that is better than ever.

Consumers and employers must continue to tell us what they want, and health care professionals must find the answers. It's all about satisfying the customer and putting a cap on spending. And the two are not incompatible.

We need to work together to meet this challenge. America can, and will continue to have the greatest health care system in the world.

Dr. Henderson is chairman of MediSphere Medical Management, Inc. in Birmingham, Ala. This patient- and physician-oriented company owns and operates medical practices and health centers and provides contracted management services throughout the Southeast.

Residents Embrace Employee Status, Survey Shows

Triton Communications

Cutting their ties with yesterday's medicine, young physicians are embracing employee status, according to a new survey.

The survey of 230 primary care physicians in their final year of residency, conducted by Merritt, Hawkins & Associates, a national physician search firm based in Irving, Texas, indicates that 55% of medical residents would prefer an employee salary with production bonus in their first professional position. Forty-one percent would prefer a guaranteed income subsidy in their first year. Only 4% would prefer a bank loan.

"Young physicians are not fighting the trend away from independent, fee-for service medicine toward salaried positions," said Joseph Hawkins, chief executive officer of Merritt, Hawkins & Associates. "Instead, they are endorsing it." Other results of the survey: 53% of residents surveyed would prefer a single or multispecialty group setting in their first year of practice. An additional 17% of residents surveyed would prefer an HMO or hospital employee setting, indicating that a combined 70% of residents would prefer an employee type of setting (group, HMO or hospital) over a more independent, entrepreneurial type of setting (solo, association, partnership).

"With the uncertainty in medicine today brought about by change, residents see group practices and other employee situations as the option that gives them both security and a manageable lifestyle," Hawkins said. "That's an attractive combination."

RESIDENTS IN DEMAND

Just over 50% of residents surveyed received 50 or more job solicitations during the course of their residencies, underscoring the overwhelming demand for primary care physicians. International medical graduates (IMGs) surveyed received somewhat fewer job solicitations than U.S. trained physicians. Only 30% of IMGs surveyed received 50 or more job solicitations. About 37% of final-year medical residents in primary care, defined as family practice, general internal medicine and pediatrics, are IMGs, according to American Medical Association statistics.

In addition, young physicians do not share the antipathy for managed medicine that many established physicians often express. Twenty percent of residents surveyed would prefer to work in a managed care environment, 19% would prefer not to work in a managed care environment, and 61% expressed no preference either way.

"Young physicians were trained in the era of managed care," Hawkins observed. "That is their reality and they have nothing to compare it with. To them, the 'golden age' of fee-for-service medicine is something older physicians talk about in the doctor's lounge."

When it comes to compensation residents surveyed had a fairly accurate grasp of their value in the marketplace. Just over 51% of residents expect to earn between $100,000 and $125,000 their first year in practice.

"In primary care, where physician compensation is rapidly rising due to demand, a first year salary or income guarantee of $125,000 is not out of line," Hawkins said.

TIMING AND LOCATION

When residents decide on where to establish their first professional practice is a matter of significant interest to anyone who is recruiting. Fifty-seven percent of physicians surveyed indicated that they began a serious search for a practice a year or more before the end of their residencies. Health facilities intent on recruiting residents would be well served to begin the recruitment process while residents are still in their second year, Hawkins said.

"Those health facilities that wait to contact physicians in the last six months of their residencies have probably missed the boat," Hawkins noted.

In addition, when selecting a practice, 70% of residents surveyed responded that the geographic location of the setting was the first or second most important consideration.

"Location obviously is very important to young physicians seeking a practice," Hawkins said. "However, location is a factor over which a recruiting hospital or medical group has no control. Recruiters should therefore make sure that they get maximum use out of the factors they can control, particularly the incentive package."

Unlike many professionals coming out of training,

young physicians are not primarily concerned about finding a job. Their main concern is finding a practice setting that is right for them. About 35% of physicians surveyed indicated that doubts about the medical setting that is right for them is their main concern before entering private practice. Hawkins suggests that many young physicians could benefit from doing temporary locum tenens work prior to taking a permanent position.

"By doing locum tenens, young physicians can determine what is right for them – a group, a partnership, an HMO – without making a hasty professional marriage that may end in divorce two years later," Hawkins observed. Despite the grueling hours and stress of medical training, 91.5% of physicians surveyed said they would select medicine if they had their education to do over again.

BAITING THE HOOK

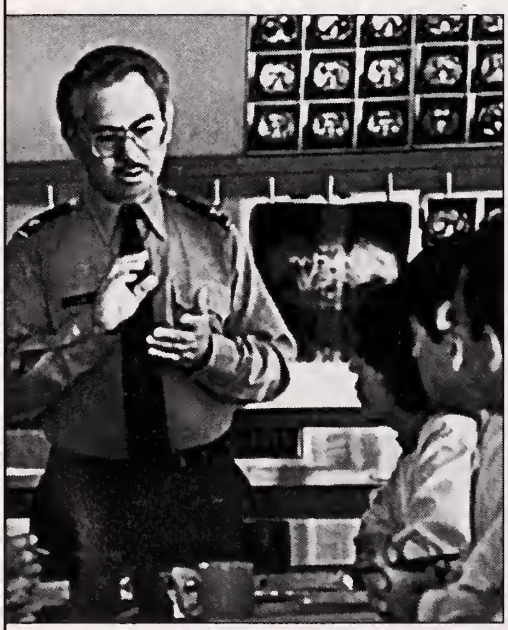
The survey holds several suggestions for those recruiting physicians, Hawkins notes.

"First, be on time," Hawkins said. "Reach out to residents a year or more before they graduate and plan out your staffing needs at least one year in advance. Second, residents have a pretty good idea of what they are worth, so know what's competitive in the marketplace and be prepared to match it. Third, structure income in a way that is attractive to residents. A salary with a production bonus is ideal."

Finally, said Hawkins, "remember that in recruiting primary care physicians you are literally competing with 50 other health care providers" for the services of residents.

Those with questions concerning the survey may call Merritt, Hawkins & Associates' Irving, Texas office at (800) 876-0500.

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Fatal Post-Cesarean Endometritis:
Report of Two Alabama Cases

Kim M. Parker, M.D.
Joseph H. Embry, M.D., J.D.

ABSTRACT

Postpartum endometritis remains a major cause of morbidity in the puerperium with a fatal outcome on occasion. We present two cases of fatal, post-cesarean endometritis which occurred within a fifteen month period in Alabama. We discuss the features of endometritis including pathophysiology, causative organisms, risk factors and complications.

INTRODUCTION

Post-cesarean endometritis remains a major cause of obstetric infectious morbidity. The incidence varies considerably, depending on the patient population and institution being studied. The persistent high rate of cesarean section deliveries in the United States, estimated at more than 20% of all deliveries,[1] is considered a major determinant of postoperative infectious complications, including endometritis.[2] Most cases involve a polymicrobial infection reflecting the diverse flora of the female genital tract. In spite of numerous antimicrobial regimens used prophylactically to reduce the rate of postoperative endometritis, treatment failures are common. Maternal deaths are rare, with few reports of fatalities directly related to puerperal infection.

CASE REPORTS

Case 1

A nineteen year old black female was delivered by cesarean section indicated by venereal warts and spontaneous labor on June 27, 1993. Her hospital course was uneventful and she was discharged in stable condition. She presented to the emergency department of a local hospital on July 2, 1993, the fifth postoperative day, with a three day history of nausea, vomiting and abdominal pain. She reported minimal lochia. On physical examination she was afebrile with heartrate 120 bpm and blood pressure 140/90 mmHg. Her abdomen was soft, diffusely tender, with marked fundal tenderness. White blood cell count was normal (8100/μ1) with 77 percent band neutrophils, 2 percent segmented neutrophils and 10 percent metamyelocytes. She was diagnosed with endometritis and given one gram Rocephin by intramuscular injection. She was discharged in stable condition at 2245 hours on July 2, 1993 with instructions to complete a course of oral antibiotics and to follow-up with her primary care physician in two to four days. She was found unresponsive by her family at 0600 hours on July 3, 1993.

Postmortem examination revealed endometritis and terminal aspiration of gastric contents. The uterus was enlarged, measuring 14cm in greatest dimension, with an intact suture line on the anterior aspect. The endometrial lining was malodorous, dark red-brown and measured up to 0.5cm in thickness. Microscopic examination revealed focally necrotic and hemmorhagic decidua with marked acute and chronic inflammation. (FIGURE 1) Postmortem cultures of the



Figure 1: *Inflamed, hemorrhagic and focally necrotic uterine decidua. Postmortem cultures were positive for* E. coli *and* C. albicans. *(Hematoxylin and Eosin; original magnification X 40).*

Corresponding Author/Reprint Requests – Joseph H. Embry, M.D., J.D. – Alabama Department of Forensic Sciences, 101 South 13th Street, Birmingham, ALabama 35205-3498, (205) 933-6621.

endometrium were positive for *Escherichia coli* and *Candida albicans*. Postmortem blood cultures were positive for *Bacteroides capillosus* and *Peptostreptococcus asaccharolyticus*. Bacterial stains of the endometrium showed abundant gram-negative rods and gram-positive cocci, many in short chains. Sections of the pancreas and adrenal glands revealed acute inflammation in the adjacent adipose tissue and in the interstitium of the head of the pancreas. (FIGURE 2) Gramnegative and gram-positive rods and

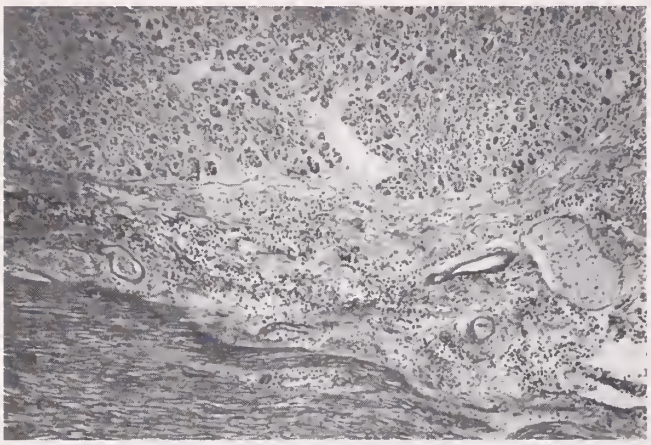


Figure 2: *Acute inflammation in peripancreatic soft tissue. (Hematoxylin and Eosin; original magnification X 40.)*

numerous gram-positive cocci, occasionally in chains were seen within the periadrenal and peripancreatic soft tissues. (FIGURE 3) The cause of death was deter-

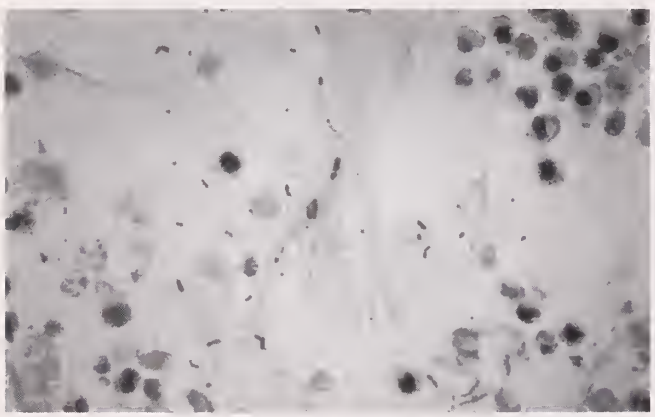


Figure 3: *Gram-negative rods and Gram-positive cocci within the periadrenal adipose tissue. (Tissue Gram stain; original magnification X 1000).*

mined to be endometritis.

CASE 2

A nineteen year old, gravida 2, para 1, white female was admitted for elective induction of a forty-one week gestation pregnancy after an uncomplicated prenatal course. At the time of admission, she had a mildly productive cough and a low grade fever. She underwent artificial rupture of membranes which showed light meconium staining of amniotic fluid. A Pitocin drip was begun and the subject labored actively for several hours. She continued to have fever up to 102°F. White blood cell count was slightly elevated at 12600/µl. With thickening of meconium and failure to progress, she underwent cesarean-section delivery and received intravenous Claforan. Uterine cultures were positive for Group B *Streptococcus (Streptoccus agalactiae)*. Anaerobic cultures were negative. She was discharged in stable condition October 21, 1994, the third postoperative day. The subject did well at home with no complaints of pain or discomfort according to her family. She was last seen watching television at 2400 hours on October 26, 1994. She was found unresponsive and cyanotic at 0650 hours October 27, 1994. She was pronounced dead on arrival at a local hospital.

Postmortem examination revealed an enlarged uterus, 11cm in greatest dimension. The endometrial cavity appeared dilated and was covered with red-brown decidua. The right ovarian vein was filled with a 12cm x 1.7cm thrombus which extended superiorly to the inferior vena cava, protruding into the caval lumen. Histologic examination showed marked acute and chronic inflammation of the endometrium with confluent aggregates of polymorphonuclear leukocytes

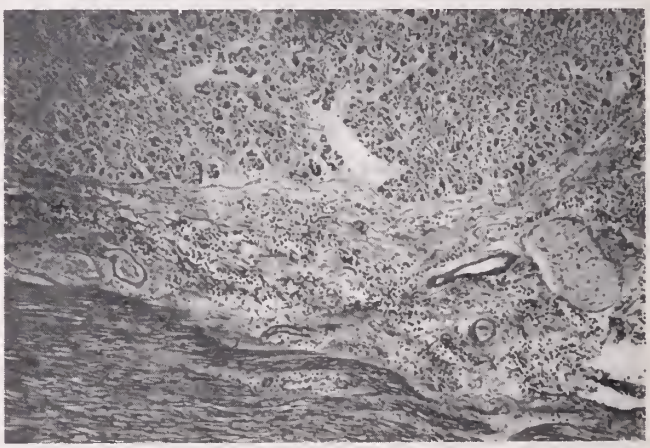


Figure 4: *Confluent aggregates of polymorphonuclear leukocytes infiltrating the myometrium. (Hematoxylin and Eosin; original magnification X 100).*

within the decidual lining and myometrium. (FIGURE 4) Sections of the thrombosed right ovarian vein showed leukocytic infiltration of the vessel wall and clot, consistent with thrombophlebitis. (FIGURE 5) Postmortem cultures of the endometrium were positive for abundant **Enterococcus**, Group B *Streptococcus* and a few *Candida albicans*. The cause of death



Figure 5: *Right ovarian vein with organizing thrombus and leukocytic infiltration of the vessel wall. Arrow denotes residual lumen. (Hematoxylin and Eosin; original magnification X 40).*

was determined to be endomyometritis with pelvic thrombophlebitis.

DISCUSSION

Postpartum endometritis is clinically diagnosed by the findings of uterine tenderness, purulent uterine discharge, fever and exclusion of other sources of infection.[3] Early onset endometritis, i.e., occurring within forty eight hours of delivery, is usually seen after cesarean section.[3] This form of endometritis is thought to begin with ascension of bacteria into the intrauterine cavity during labor with contamination of the endometrium and uterine incision line at the time of delivery.[3] Cellulitis, bacteremia, lymphangitis, endomyometritis or septic pelvic thrombophlebitis may result.[3]

Late postpartum endometritis tends to be clinically mild and is thought to be secondary to ascension of vaginal or endocervical bacteria into the endometrial cavity with infection of the placental site, decidual lining or uterine incision site.[3]

Mixed facultative and obligate anaerobic organisms are usually present, reflecting the diverse flora of the female genital tract. The organisms most commonly isolated include: *Gardnerella vaginalis, Enterococci, Streptococcus viridans, Staphylococci, Lactobacillus, Diphtheroids, Escherichia coli* and *genital mycoplasmas.*[3,4,5,6] Anaerobic pathogens include *Peptostreptococci and Bacteroides.* [3,4,5,6]

The incidence of postpartum endometritis depends on the patient population and institution being studied. Clinical endometritis has been reported in <1% to 5.9% of postoperative cesarean section patients who received prophylactic antibiotics and were delivered in a private setting.[2,7] Other authors report an incidence as high as 10% to 20% in a similar patient population despite the use of prophylactic antibiotics.[4,8,9] Among patients who do not receive prophylactic antibiotics, the incidence of postpartum endometritis ranges from 3.5% of patients delivered in community hospitals,[7] to 95% of untreated indigent patients with positive amniotic fluid cultures.[3,10,11,12] The overall incidence of postpartum endometritis occurring after vaginal delivery is estimated at 2%.[9]

Fortunately, maternal deaths related to obstetrical infections are extremely rare. Shanklin et al. reported that of 281 maternal deaths studied over a twenty year period, only 16 deaths could be directly related to sepsis/infection.[13] Of these 16 cases, 10 were similar to the current cases presented.

The literature is replete with studies describing various risk factors for development of post-cesarean endometritis. Ehrenkranz et al. found significant correlations between increased risk of endometritis and: active labor, being unmarried, lack of timely antibiotic prophylaxis, primary cesarean section and having three or more vaginal examinations.[7] A retrospective study by Magee et al. demonstrated that teenagers are at greater risk for post-cesarean endometritis than advanced maternal age patients when the groups were matched for length of labor, length of rupture of membranes and use of prophylactic antibiotics.[14] Differences in vaginal and cervical flora, larger numbers of sexual partners and differences in host defenses are thought to be responsible for the higher infection rate in the younger age group. In the current cases, both subjects were nineteen years old and delivered by cesarean section.

A rare complication of endometritis, occurring in 0.04% to 0.18% of obstetric cases,[15,16] is septic pelvic thrombophlebitis, as described in our second case, with thrombosis of the right ovarian vein extending to the inferior vena cava. Spread of infection to the pelvic veins is thought to be related to infectious injury to the vascular endothelium, venous stasis and hypercoaguability of the puerperium.[3] Patients may be asymptomatic or may present with nausea, vomiting, flank and lower abdominal pain, or fever.[16] This diagnosis should be considered in postpartum patients with persistent fever, despite the use of broad-spectrum antibiotics.[15] CT scans have been helpful in establishing the diagnosis in some cases, as well as the presence of a rope-like mass on abdominal examination.[16]

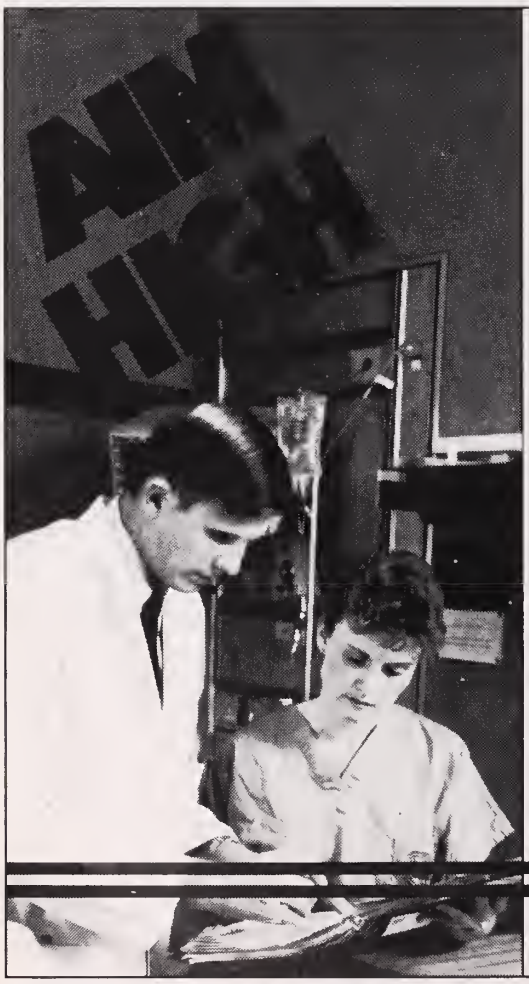
Among the bacterial organisms associated with endometritis, the Group B *Streptococci* (GBS) pose one of the most dangerous threats to the neonate. GBS infections are the most common cause of life threatening bacterial infections in the newborn infant with an incidence ranging from 0.6 to 3.7 cases per 1000 births.[17] Most infants acquire the infection via vertical transmission from their mothers, especially with heavy bacterial colonization of the maternal genital tract. While GBS infection was documented by intrapartum uterine culture in our second case, there were no signs of neonatal sepsis. The mixture of facultative

and obligate anaerobic organisms associated with postpartum endometritis requires combination antimicrobial therapy for effective treatment. While various regimens of prophylactic antibiotics have demonstrated efficacy in reducing the rate of postpartum endometritis,[2,4,5,18] treatment failure has been estimated to occur in up to 50% of patients.[2] This failure is thought to be related to histologic evidence of incipient infection[2] and infection with B-lactamase producing organisms.[18]

In summary, postpartum endometritis remains a major cause of puerperal morbidity with a rare fatal outcome. Serious complications may be avoided by anticipation of infectious morbidity, especially in high risk patients, with early recognition of clinical symptoms and timely administration of antibiotics.

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*Dennis G. Pappas, M.D.**

INTRODUCTION:

In keeping with the purpose of all posters, those that are medically oriented are intended to sell a product or concept. There is evidence that they were used to sway public opinion as early as the 17th Century; however, these earlier posters were not often illustrated. For example, a 1683 German poster gave warning of the plague and posters expounding on the benefits of patent medicines were frequently used by 1840.

From 1880 to 1905, particularly in the more rapidly advancing industrial countries of England, France, and The United States, illustrated posters became recognized as an art form. The signature of several of the major artists of that era, such as Toulouse-Lautrec, Jules Cheret, and Eugene Grasset, could be found on many of them. This, undoubtedly, contributed to the popularity of poster collections in the late 19th and early 20th Centuries. W. H. Helfand, who cites that period as the golden age of posters, reports of a 1891 catalog of 2,200 items for sale by Edouard Sagot of Paris.

In contrast to the early illustrated posters of Europe, American posters designed before 1890 were prepared by commercial printers and were unsigned. One exception was a poster done by the American lithographer, Will Bradley, in which a red-haired beauty is depicted lauding the "pure blood" provided by Nood 's Sarsaparilla. Another exception, a poster for No-To-Bac done by the American illustrator Maxfield Parrish, was prophetic in warning of the dangers of smoking. Until their use was curtailed by the 1906 Food and Drug Act, most of the medically oriented posters were directed to sell nostrums. Some, however, were intended to relay general information regarding health and benefits to raise money for the victims of such diseases as cholera and tuberculosis.

The use of posters allied to medicine began to wane in the early 20th Century, during the time those propagandizing the First World War and the Russian Revolution began to appear. In Russia, posters in general, have a long history of playing a prominent role in distributing propaganda. The modern and contemporary Russian posters in this collection suggest that they are still used as strong educational tools. In their simplicity, they effectively manipulate color and design to appeal to emotions and reason in an effort to influence the public about drug abuse.



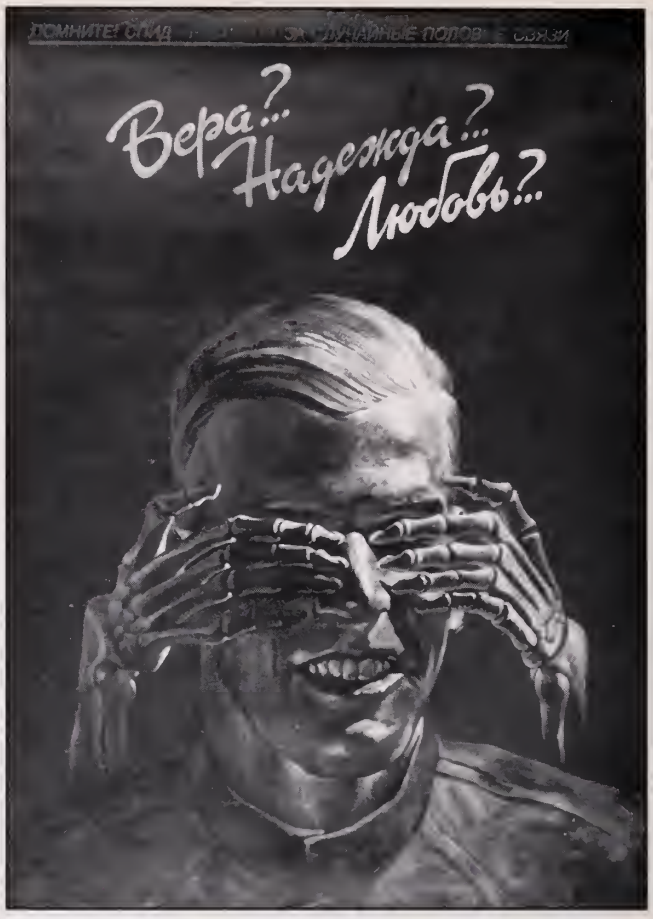
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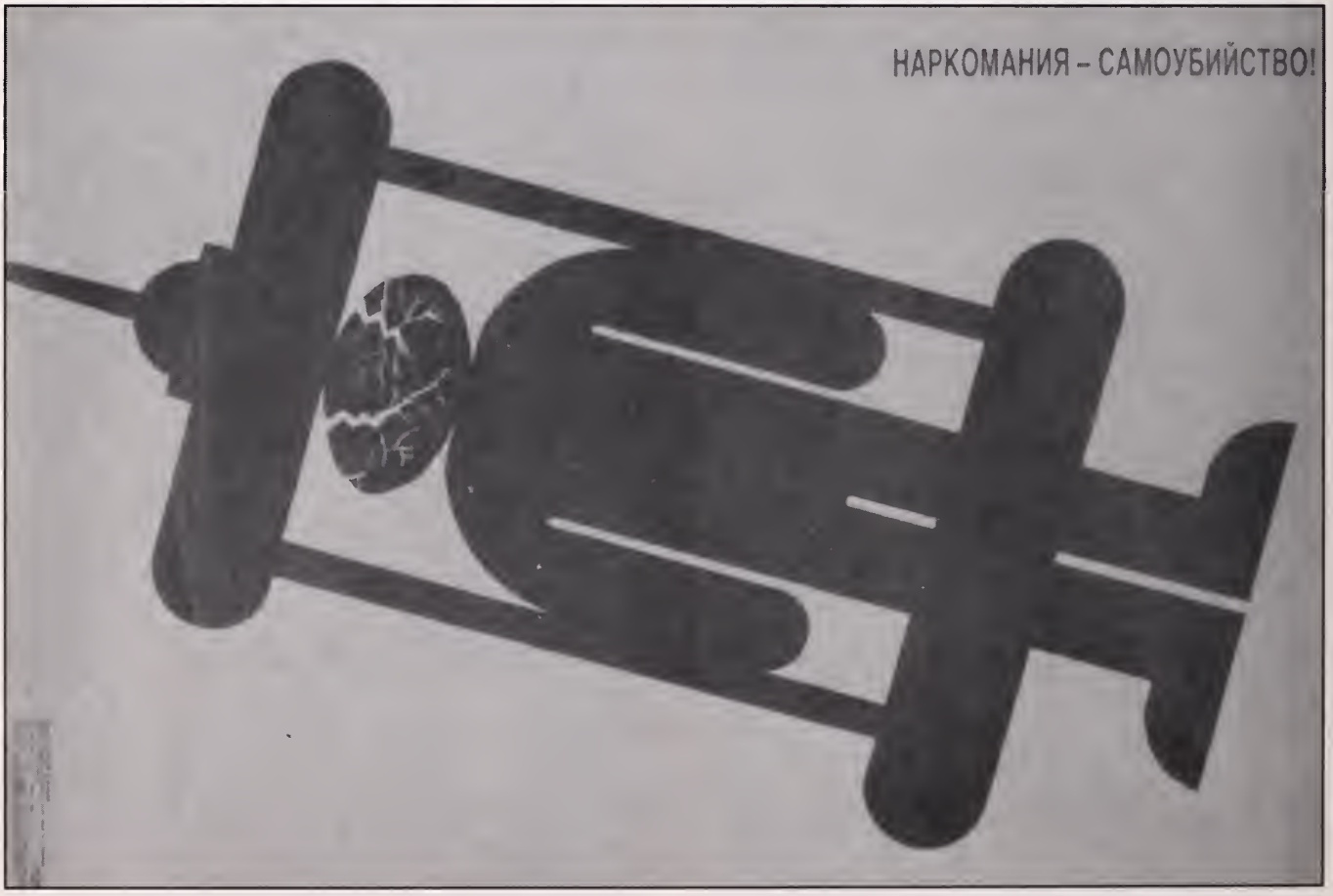

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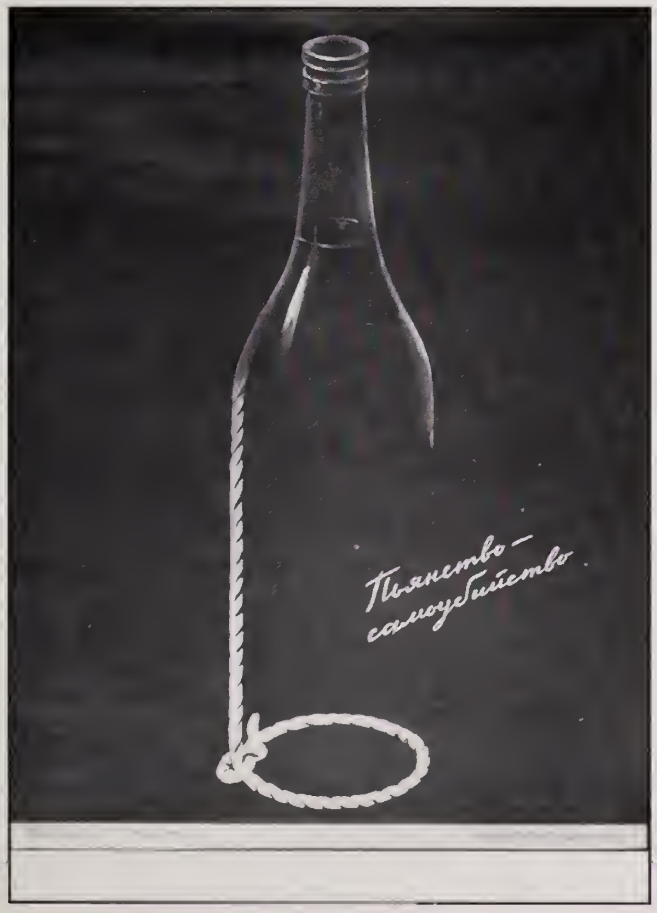

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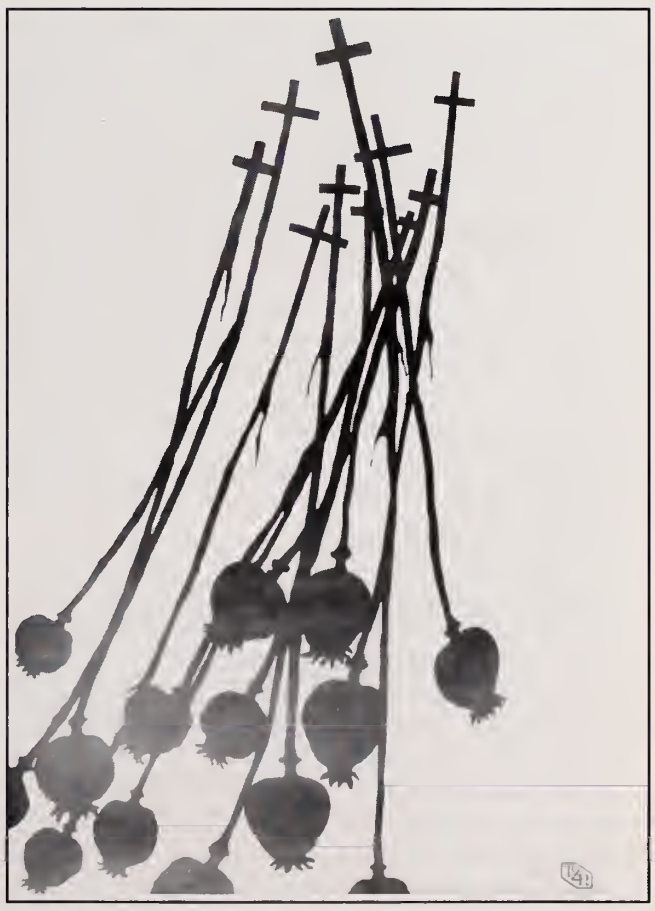



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ALLIANCE:



Donna Gosney
A-MASA President

Positive Thinking = Positive Results

The impact of the health projects sponsored by Alliances in communities across Alabama is somewhat overwhelming. Without the Alliance, many children would not receive immunizations, education in many topics ranging from bicycle safety to AIDS education or, even, the basics of food, clothing and shelter. There would be no puppet shows encouraging children to speak up in cases of abuse or neglect. There would not be a Chrysalis Home for girls, a Camp Rap-A-Hope for children with cancer or a mobile educational facility such as Body Trek. There would not be funds to donate to shelters; to provide scholarships; or to buy literature to distribute throughout the community. Volunteers for Adopt-A-Schools, hospitals and programs on spinal cord injuries would not be available. Money would not be available for an AIDS Hospice or baby mannikins for parenting classes. The Alliance is committed to promoting good health in our communities, and we can have the most positive influence on the image of the medical family. Through our actions, we spread the word that we are extremely proud of our physician spouses and their profession.

Even though the pressure seems to have abated, we have been reminded many times by Legislative Chairman Anne Marie Gormley that we cannot relax the vigil. It is more important than ever to become familiar with your legislators. The focus has become a grassroots effort as AMA and the AMAA build phone banks of legislatively active members across the nation.

In order to maintain quality in the medical field, we must continue support of the American Medical Association education and Research Foundation. The monies donated to the Foundation insure the future of medicine by supporting quality education. More than $2,000,000 has been raised nation-wide each year for the last four years. Nita Maddox, AMA-ERF Chairman for Alabama, will present a portion of these funds to Alabama Medical Schools.

As President, I would like to express my appreciation to the Medical Association of the State of Alabama. They are always supportive of our plans and programs. The Alliance has joined forces with MASA in health programs and legislative activities, and we hope to increase that interaction in the future.

I would like to express my gratitude to the Alliance to the Medical Association of the State of Alabama for giving me this opportunity to travel across the state meeting the members. It has been the most moving experience of my life. My respect and love for this organization has grown, and it has enriched my life. I am extremely proud the members have proven that positive thoughts and actions can transform our organization into a force that will change lives across the state. I want to add my thanks to Frankie Armstrong, our Executive Staff Assistant at MASA. She has been an invaluable aid and good friend this year.

Usha Bhuta will be the AMASA President for 1995-96. I offer my support and assistance to her and the board.

Donna Gosney, President
Alliance to the Medical Association of the State of Alabama 1994-95.

It has been both an honor and a pleasure to serve as President of the Alliance to the Medical Association of the

State of Alabama for 1994-95. As I visited the counties, it astounded me to learn of the many projects and programs being sponsored by Alabama Alliances and Auxiliaries. I began this year by encouraging members to become a positive force in promoting health care in Alabama. I had no idea of the results obtained by thinking positive, acting positive and becoming a positive organization.

1994 was a stressful year for medical families. It seemed that negative feelings were bombarding us from every angle. It got to the point that many of us were even reticent to admit that we were members of the medical family. My goal was to return pride to the medical community. We are married to physicians who provide the medical community. We are married to physicians who provide the greatest medical care in the world. We have reason to be proud of them, of the medical profession and of the Alliance and its programs to promote good health. Therefore, we have to change our thinking to a positive line. We have to spread the word about our organization and its work. To that end, Barbara Tippins, President of the American Medical Association Alliance, announced the inception of Medical Alliance Month. Beginning this year, March will be designated a month in which to publicize the Alliance and its activities.

To assist in changing to a positive frame of mind, our Fall and Winter Leadership meetings focused on stress as it affects the medical marriage; how it can lead to physician impairment; and ways to relieve and alleviate stress.

County officers and committee chairmen received training on state and national levels. The Fall Leadership Conference offered training by our state officers and committee chairmen in Membership, Health Projects, Legislation, Parliamentary Procedure and AMA-ERF. Ten county President-elects and a Medical Resident's spouse attended the Leadership Confluences held by the American Medical Association Alliance in Chicago where they attended sessions on all aspects of the Alliance as well as public speaking, time management, and working with the media.

Emily O'Toole wore two hats this year. As membership chairman for Alabama, she worked with our counties to provide materials and support in the endeavor to recruit and retain members. This is a never-ending campaign in which we must seek ways to let all know that the Alliance needs their support in order to continue to provide the community with quality projects that promote good health. Our goal is to have every physician's spouse become an active member. We urge those who feel that they can not devote their time and talents to the Medical Alliance to support us with their dues. The money will enable counties to continue their valuable work. As Southern Medical Councilor for Health, Emily publicized the Breast Cancer Awareness Program sponsored by the Southern Medical Auxiliary. As a state project, she purchased a prosthesis that can be used to train women the correct method of breast self-examination.

As Second Vice-President for Health Promotion, Fran Barksdale kept us aware of the assistance we can receive from the AMAA. The number of materials is amazing and growing continuously. The training at the Fall Board enabled many counties to plan health projects for the year.

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The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International*, Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

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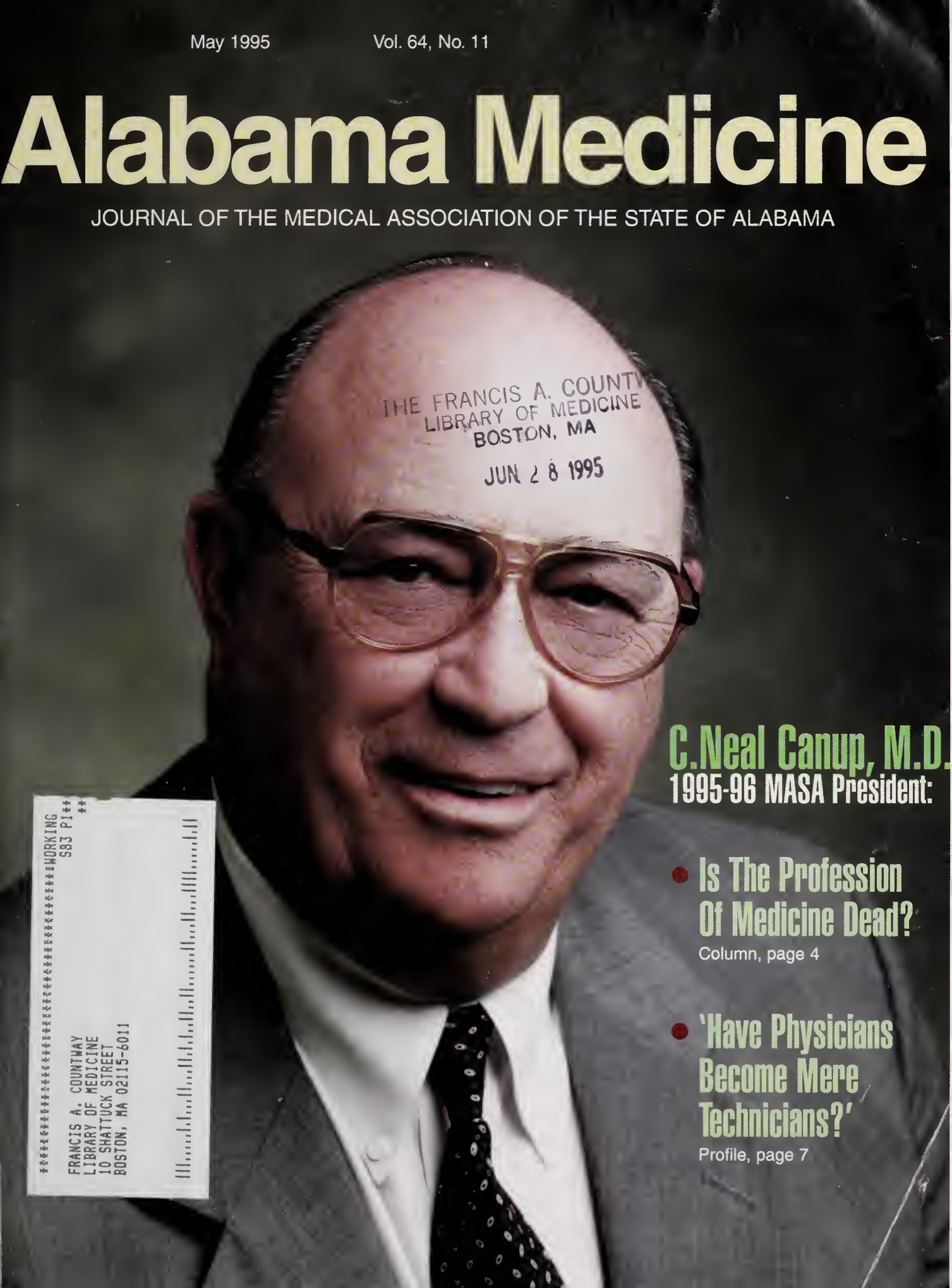
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C.Neal Canup, M.D.
1995-96 MASA President:

- **Is The Profession Of Medicine Dead?**
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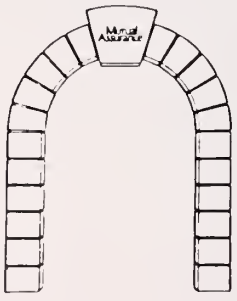
- **'Have Physicians Become Mere Technicians?'**
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S. Lon Conner
Executive Director, MASA

MASA Director Claims Newspaper Article Biased

This month's column first appeared on the opposite editorial page of The Montgomery Advertiser *April 18. Mr. Conner is responding to the extravagant language and misinformation in one of the recent installments of that newspaper's running series, "Doctors Watching Doctors." – Ed.*

The long running series of articles in *The Advertiser* — "Doctors Watching Doctors" — has been one of the most zealous attacks on medicine I've witnessed in my 18 years with the Medical Association. So zealous, in fact, that some of the news reporting has crossed the boundaries into editorializing and "selective reporting," which we do not feel is professional nor in the public interest.

As an example, *The Advertiser* reports in its article, "The Doctor's Out" (April 10), that Eclectic, a small town 26 miles east of Montgomery, is doing without the services of a physician and is without health care services at all.

"Desperate," reads the sub-head. "One month after Eclectic's doctor left for a family practice in Montgomery...," the story continues, which would lead the reader to believe that the town now has no doctor.

The truth is that Eclectic has a practicing physician — Dr. Jerry Bush — who has been in practice for eight years and is currently caring for a patient base of several thousand people. Dr. Bush was not contacted for comment on the status of health care in Eclectic and was not mentioned in the article. (The reporter also chose to ignore Mayor Charles Worthy's positive comments about Dr. Bush.,

Eclectic — which was labeled "doctorless" in the news article — does, in fact, have a well qualified and competent physician available. That fact simply was not reported.

The focus of the article was on the Eclectic Medical Center, which has lost its physician and is in need of another doctor in order to reopen. The Medical Center has been an excellent resource for medical care for indigent patients in the Eclectic area, we are told by Mayor Worthy. And, certainly, we understand the need for this clinic and are concerned for patients such as Mrs. Banks who utilized its services.

However, the article exaggerates for effect and implies that the Medical Association is to blame for Eclectic patients in need of medication having to "drive to Montgomery more than 30 miles away" when drug stores are available in both Tallassee (12 miles) and Wetumpka (15 miles).

Other facts were omitted as well. Dr. Calin Braicu, who was the doctor at the Medical Clinic and is now practicing in Montgomery, told us that he left Eclectic because there simply was not a high enough demand for the services of two physicians. There were many afternoons he was "open" with no patients. (This never made it into the news story because Dr. Braicu was not contacted by the reporter either.)

Dr. Braicu also commented that the clinic requires

the expertise of a physician.

"The kinds of problems we saw in the clinic need to be handled by a physician," he said. "A nurse practitioner could handle it under the supervision of a physician, but not having a physician physically tied with the clinic would be totally inappropriate."

Which brings me to another misleading point made in the article. The sub headline reads, "Some say Alabama's Medical Association has kept nurse practitioners from filling a void in Eclectic and elsewhere."

The Medical Association is blamed "for the health care crisis in towns such as Eclectic." This could not be further from the truth.

The Medical Association introduced legislation during the 1994 session (which was endorsed and supported by *The Advertiser* on its editorial page) which provided for prescriptive authority for nurse practitioners and physician assistants.

The physicians assistant bill passed and became law. The nurse practitioner bill died in the House due to the heavy lobbying efforts of the Alabama State Nurses Association.

Prior to this legislation being introduced, a series of meetings took place between members of the Medical Association, the Board of medical Examiners, the Alabama State Nurses Association and the Alabama Board of Nursing in order to bring about the necessary legislation to provide for prescriptive authority for nurse practitioners.

Due to an uncompromising position taken by a small, militant group within the Nurses Association, no agreement was reached. The truth in the matter is the Medical Association was stonewalled on this issue.

The story states that, "Nurse practitioners said putting them under the doctors would give the state physicians' group the right to regulate them out of business..."

The fact is that the legislation proposed by the Medical Association as a compromise bill — which was rejected by the Nurses Association in the final days of the 1994 legislative session — called for joint regulation of the collaborative practice of a physician and a nurse practitioner by the Board of Nursing and the Board of Medical Examiners.

Since many of the elements of nurse practitioner practice are in part medical practice performed under a protocol entered into which a supervising physician, the Medical Association felt then and continues to believe that such joint regulation is necessary and appropriate to protect the public health. This approach with joint regulation has proven successful in a number of other states.

There are no simple answers. Those in the news media who are quick to place blame on physicians do not fully understand the intricacies of the problem, nor do they seem willing to take the time to adequately report all the facts.

The Medical Association's role in public health and the licensing of physicians goes back well over 100 years. We agree this system is not perfect. But, inflammatory, misleading news articles will not help. Rather, this places further wedges between the people and organizations they must work together to bring about positive change.

PRESIDENT'S PAGE



C. Neal Canup, M.D.
President, MASA

Is the Profession of Medicine Dead?

First given by Dr. Conup at his installation as MASA President, Birmingham, April 1995.

Is the profession of medicine dead?
Is the profession of medicine dying?
Can the medical profession be resuscitated to good health?

Many people have written about this subject and, in my opinion, most notably, is Jaques Barzon, Who wrote an article entitled: *The Professions Under Seige* published in *Harper's* Magazine in 1978. A year or two ago, this article was shared with many of you, as well as myself, by Mr. Bill McDonald. I would suggest to you that this should be required reading for everyone. Many remarks that I share with you are taken from this article.

In the past few years it seems that we have spent most of our energies and our resources in trying to control, or react to the changes, or threatened changes, in the traditional way medicine is practiced. I have no argument with that. I think that is a very appropriate way to use our energies. Basically, this is the purpose of the Association: t**o take care of the special interests of its members**.

But as we look at what is happening to the practice of medicine, it is my opinion, for the most part, that we have lost the battle to govern or control what happens to the practice of medicine.

Look at the number of practitioners and alternative health care deliverers out there. Herb doctors, magnetic field practitioners, homeopathists, faith healers of all types...many more than I can think of now.

There are also groups that we have sponsored...or associated ourselves with: physicians' assistants, nurse practitioners, nurse midwives, nurse anesthetists, pharmacists, respiratory therapists physical therapists, nutritionists, and I am sure there are more on the way.

There are more different levels of competence, or incompetence, in every community taking care of patients than there was in the day when Flexner made his historic report about medical education in this country in 1910.

My thoughts are that maybe one of these days, the only difference between us and those in the aforementioned group would be our profession.

The modern use of the word profession has come to refer primarily to any type work or endeavor as one's "profession." The word has been so misused that it ends up not carrying the old, or the traditional definition.

As you well know, medicine was one of the historical three learned professions, or privileged professions if you will. That is, law, medicine, and the clergy.

First, I would point out to you that all of those that were considered learned professions, were of people who **served**. Or, to put it another way, people who had a higher moral motive than just profit. I will talk more about that a little later.

What makes a profession?

Three things, I believe:

First, a profession has a distinct practical purpose. Our purpose is to deliver health care or to practice medicine.

Second, A profession requires some special learning or training.

Ours obviously does.

Third, a profession must have a higher moral purpose than the profit motive. Or, put another way: what we do is so valuable or important to the citizens that it must have a high moral purpose.

If it does not have all three of these, and in particularly the third, then it is a trade. We have gone to trade school and we practice a trade, like any other tradesman. A profession does not exist for itself.

For example: I practice medicine for my living. The profession of Medicine is a way of life. It is a privileged way of life. Privileged not to be rich. Privileged not to be arrogant. Privileged not to be higher social class. **But privileged because we serve.** We have been given a good basic education, a good technical education. Our friends and our neighbors still believe in us at a 93% level, which is phenomenal. We are still given many opportunities to serve outside the practice of medicine. Many doors have been opened to us.

I know many of you are saying, "Come on! Canup, at least take a giant leap into the 19th century."

You are telling me that medicine is a business, the overhead is there, the children are in school, tuition must be paid, the mortgage must be paid, liability insurance must be paid, not to mention the taxes.

I know...I know...how well I know!

But, I also know that what we do has more value than the maximum allowable charge...

I will repeat that,

What we do has more value than the maximum allowable charge. Thomas Moore has written numerous books...one of which was entitled *The care of the Soul*. I am not trying to make an equation, just to borrow a phrase.

The profession is in need of some care. It is long past due. We have been so consumed with what we do that we have forgotten what we are about and why we are a profession.

What can we do on a more practical level?

How can we be professional at the age of planned care, HMOs, PPOs, et cetera?

How can we be professional when competition is increasing and will increase even more? How can we stay professional when technology is changing the shape and face of the whole world of health care and health care delivery? How can we stay professional? How can we care for the profession under all these conditions?

It can only be done individually and personally.

Any profession is judged by its lowest level. I am sorry that this is true, but it is.

First — If we stay a profession there must be, in truth, self-discipline and believable self-discipline of the profession.

Second — We must learn to be kind to each other.

When competition increases, historically, we have turned on each other. When one group of practitioners become recognized, we tend to attack them. I say to you that our colleagues are not our enemies. The people who would say that our profit margin is more important than the health and well-being of our patients — they are our enemy. Colleagues are not your enemy. If you are going to fuss and fight with them, **you are wasting your energies**. You will never control your practice, or put them out of business by attacking your colleague. It is the most non-professional behavior to see physicians attacking each other, when what we need to do is to be more kind to each other.

It has been my contention for years that all people need three basic things in life:

They need to be recognized.

They need to affirmed.

They need to be loved.

We don't do that for each other very well. We need to take the high road. We need to supply each other with care.

Third — each of us must make the decision with every patient we see, to do something of quality and that our interests in their health and well-being is more important than their pocketbook and more important than their, or our, employer's profit margin.

Fourth — who else can contribute? Medical schools can help. They can help by making as sure as possible, up front, that the people who are chosen have a dedication to a way of life. Making sure that at every opportunity they stress what the reward of this profession is...and that is service. Establishing that the professors have a concept of what the profession is. Including in the residency curriculum both the traditional medical content and, **just as important**, how you practice medicine.

How do you stay a professional for 30 and 40 years and enjoy your life and work?

Again, I will go back to what I said in the beginning, and that is that the person who is responsible for being a professional, for upholding the profession, is you and me as individual practitioners of medicine.

Briefly, we have discussed the three things that I believe make a profession. Those three things that I believe make a profession. Those three things also embrace some behaviors and I would stress to you that behaviors are not looks. I am not talking about whether you have an earring in your ear...Long hair, no tie, wearing blue jeans. A professional is not an appearance or a look. It is a behavior and a sensitivity.

To be a professional not only requires us to be good practitioners, but it also requires us to be good citizens. To be involved in our community. To be involved socially, civically, religiously, politically, however. But be involved.

We have been given much, and much is required of us. I don't need to give you a reference to that statement.

In closing, I would like to tell you a story about a

young man named Carter. He was born in the mountains of North Carolina around the turn of the century. I heard this story on my automobile radio while traveling between Anniston and Montgomery one day. Carter had gone to primary school, or grade school, finished number one in his school. There was not a high school in town and discussion with his family was that they could not afford for him to go away to high school because they had no money. The father said, "obviously, we don't have the money, but I will give you a cow. You can milk this cow and earn enough money to pay your way to high school." Which he did.

I must say, don't worry children, I am not telling a poor daddy story.

But, Carter finished high school, where, again, he graduated first in his class and was given a scholarship to Johns Hopkins.

Again, graduating magnum cum laude.

He went on to medical school, finished first in his class. Was offered all types of training programs and teaching positions around the world. He chose to go back home. He came back to his home community. The town area had two or three buildings, one paved street, and one of the buildings had two floors. Access to the second floor was by an outside stairway and up on the second floor is where Dr. Carter opened his office. Down on the street level at the corner of the building was sign that said,

"Doc Carter...upstairs."

For 50 years Dr. Carter served that community. He delivered their babies. He set their broken arms. He held their hands as they were dying. He served on the school board. He served in the local government. He contributed advice and education for 50 years. He served that community. He was never president of a medical association. He was never a member of the Board of Censors. He simply served his community.

He retired after 50 years and a few months later he died of a heart attack. The community had never seen that many people attend a funeral. His death was celebrated all over that part of the state.

A few weeks later, at a town meeting, they were trying to decide a fitting memorial to "Doc" Carter. They discussed naming the main street after him. They discussed a large granite monument. They discussed epitaphs. Finally, a young man spoke up who had much love and care for Doctor Carter, because Doctor Carter had exemplified all kind of professional behavior to this young man, not only in his health care, but in his personal life. The young man said, "I know." He ran out and around the corner and pulled a sign off of the wall and came back and said. "On a simple marker this what it must say. 'Doc Carter...upstairs'."

I do not tell this story so we can get busy about our epitaphs, or our memorials. I tell the story as an example of a professional who held up his part of the profession.

I will repeat: the profession needs some care. What we do surely must have more value than the maximum allowable charge. What we are must be more important than our income, than our social status.

I repeat: **a profession must have those three aspects.**

A specific view of what it is to do requires special training and it has a higher moral motive. I would say that we have learned to talk and we have learned the language of the profession. My mother used to tell me, after we had discussed in detail some chore or problem that I did or did not want to do, "Now son, it is time to put arms and legs on your mouth!" In modern language we would say, we have learned to talk the talk, it is time for us to walk the talk.

Let us say no, the profession is not dead, but, yes, I believe it is in danger of dying.

Let us join together and give the profession some care.

Thank you.

Dr. Canup:

Have Physicians Become Mere Technicians?'

by William H. McDonald

When, more than 40 years ago, C. Neal Canup joined the Navy, it was not because of any irresistible hankering to see the world, although you might suspect that from his origins.

Born in a small sawmill community in the Blue Ridge mountains of Northeast Georgia, the 1995-96 President of MASA also admits today that he had no burning aspiration for education beyond high school; after graduation, he went to work in a cotton mill. If there was somewhere in his psyche a hunger for wider horizons, it was not troubling him at the time.

Since his father had died two months before Neal Canup was born, economic constraints may have suppressed any thought of upward mobility. Although he did enroll in a little Baptist junior college, that was mainly to play basketball on a partial scholarship, he says today, again renouncing any thirst for knowledge. Basketball was not a means but an end.

In those days, had anyone suggested that he study medicine, Dr. Canup says with a wry grin, he would have dismissed the thought as crazy.

These are revealing disclaimers: many people who have made a success of their lives yield to the temptation to re-invent their own history – seeing, for example an anointing and beneficent destiny at work as early as their kindergarten years. They routinely discount what may have been the most important determinant – luck.

Dr. Canup, a straight from-the-shoulder, no nonsense person, is not given to such revisionism. In substance he admits that he is where he is today because he fell out of a well.

He had no real passion to join the Navy – until a draft notice got his attention. But the Navy works in mysterious ways, as will be seen.

By the time his four-year tour was over, he was determined to be a physician.

Dr. Canup chuckles when he recalls the environment of this epiphany.

In the course of his service, he was assigned to a Marine air wing in Japan. With his prior experience as a pharmacist at a Navy hospital in Charleston, chance and the Navy combined to select him as pharmacist for a 30-bed hospital on the naval air station that was the home base for the Marine fliers.

His life was about to be changed forever. The little hospital was staffed by 30 doctors; their commander was a Navy reservist, "a four striper [captain, equivalent to colonel in the other services] from Tennessee, who knew nothing about the Navy," Dr. Canup recalls.

But that didn't seem too critical in his present command: "None of the other doctors had more training than an internship."And, happily, in this curious St. Elsewhere of the Orient, there were few patients. Dr. Canup recalls:

"Once a corpsman came to one of the doctors and asked if he would see a patient. The doctor replied, 'Damn! I've already seen two today'."

What other inferences could be drawn from this experience in Japan by Pharmacist Mate Canup, lately of the Blue Ridge Mountains, than that: (1) physicians live a Life of Riley; and that (2) he could do what he had seen the young doctors do?

While this study of the medical profession could hardly be called exhaustive, the conclusions he reached in Japan, including the false assumption that medicine was a no-sweat career, sustained him after he left the Navy in 1958.

He completed his undergraduate training at North Georgia College, a military school with a fine pre-med reputation, in 1960, and received his M.D. degree from the Medical College of Georgia in 1964.

Following his training in general practice at the Columbus, Georgia, Medical Center, he headed North up the Chattahoochee to open his practice in Heflin, Cleburne County, Alabama, on the Georgia line. He had left his home state, but not by much.

After two years in Heflin, Dr. Canup moved the short distance to Anniston in the adjoining county of Calhoun. He has remained there ever since, but not always in private practice.

In 1975, he was appointed Associate Director of the Anniston Family Practice Residency Program, then served as Director of that program from 1977 to the suspension of the program in 1991, when he returned to private practice in Anniston.

All the while he has been freely and cheerfully paying his civic rent, to the profession and to his community, in an exemplary fashion that may owe more than a little to his Blue Ridge beginnings:

Vice chairman, Board of Directors, Alabama Quality Assurance Foundation; TB Control Officer, District IV, Department of Public Health; Dean's Advisory Committee, Family Practice, UAB; Cheaha District

Health Board; Academy of Family Physicians, President and member of Board of Directors, Alabama Chapter; Chairman, Board of Censors and President, Calhoun County Medical Society; Calhoun-Cleburne Mental Health Association; ALAPAC Board of Directors; Medical Director, Deckwood Manor; member, MASA Council on Medical Education; Calhoun County Chapter, American Cancer Society; Chief of Staff, Stringfellow Memorial Hospital; Chief of Medicine, Northeast Alabama Regional Medical Center; and so on.

Outside such medically related service, he has served as Chairman of the Commission on Ministry of the Episcopal Diocese of Alabama; as Vestry Member and Senior Warden, St. Michael's & All Angels Episcopal Church; he has been a Rotarian, a bank director and President of the Knox Concert Series in Anniston.

Perhaps most revealing of his profound belief in nourishing and maintaining what he calls "the soul of medicine" was his 1987 founding of a free clinic in a poor section of Anniston – St. Michael's & All Angels Community Service Center. The clinic averages 100 to 150 patients a month at a cost of less than $1,000 per month.

Although President of the clinic, he is no figurehead: he sees patients on a regular basis.

(Asked if he was raised an Episcopalian, Dr. Canup laughed: "In the mountains of North Georgia you are not raised an Episcopalian. In those country churches they wouldn't have known what that was.")

Question: Dr. Canup, what would you like to accomplish in your presidential year?

Answer: "I want to explore what is really good about the profession, those aspects of medicine we should give some needed nourishment, while not omitting the negatives.

"I want to talk about themes that are still good and sound, things that we don't seem to have time to think about anymore. You get so busy everyday, reacting to this and that, you don't have time to sit down and read and think. We spend so much time answering the telephone, reacting to the person on the other end, we don't take care of the things that should be taking care of.

"The dominant force in our society is economics. That being so, we don't have the time – or we don't take the time – to see what things really mean to us. I don't have the time for reading, recreational reading, the kind of reading and thinking that we need to open the mind to important themes that we have neglected.

"We get so tired during the day that when we do sit down at home and try to find a quiet time for reading and reflection, pretty soon the head is bobbing....

"To some extent, the medical profession suffers from the same loss of the points of reference that afflicts the rest of the country. What we discovered in our recent wars – in Korea and Vietnam – is that Americans generally are no longer sustained by the strong bonding they once had to religion, to institutions, to society.

"Basic values have taken a beating and medicine has suffered too. Do we still feel that we are professionals? Does our training even qualify us to be professionals in the broad sense of the word? I think the concept of what it means to be a professional has degenerated.

"I think that it takes a lot away to say simply that I am a good technician and as a technician I can make a good living.

"If that is all there is to the profession, it has lost the internal rewards – joy and satisfaction, the feeling of accomplishment and pride.

"We don't go home feeling good, but just feeling tired. I am convinced we have lost something very important. And part of that, I believe, can be attributed to our not having taken care of – for the lack of a better word – the soul of medicine.

"To me, being a professional means a lot more than that. A true professional does something beyond practicing medicine. He is a leader in that community. He gets involved socially, civically, religiously, politically. He contributes far beyond a technical role."

Q: Has specialization contributed to the isolation of the doctor as technician?

A: "No question. And that goes for the proliferation of mid-level practitioners too. Every time you get another subspecialty, another division or subdivision, what you are really doing is making the numbers smaller and the prices higher. I had never thought about it before in purely economic terms until I heard an economist speak. But thinking economically is the way it is: the number of physician offices and the number of hospitals set to make the maximum allowable charge for their services ...

"I understand the reason for that because you are dealing with an inanimate third party. I understand that. But the subtle part of it is that you are saying that what you do has no more value than the maximum price you can put on it.

"It's so damn subtle, we don't even know we are doing it ourselves. But it's just another way of reaching the endpoint where you go home tired very day. You come home beat up because, instead of, 'I contributed today,' and feeling the joys that go with that realization, I'm just tired. It's an empty fatigue.

"I hate to see the profession going where there is no pleasure, there is no joy, there is no satisfaction beyond how much money I can make. To me that leaves an emptiness that is not fillable. The question comes down to getting involved with your patient or not getting involved. When you get involved, there will be pain and heartache, of course, but also all kinds of joy there. If you don't get involved, there is nothing, absolutely nothing.

"If you look at the other two of the old three learned professions – law and the ministry – you will find the same thing has happened. Take law, for instance: there is no trust anymore. You and I can't make a deal without a hard and fast contract. This way of thinking aggravates me; it destroys the need for honor."

As the year progresses, MASA members will hear more on these subjects. It should be evident that when Pharmacist Mate Canup finally did begin thinking about medicine four decades ago, he didn't stop.

HMOs and the High Price of Prevention

*by Ernest S. Campbell, M.D., F.A.C.S.**

One of the main selling points of the strong push for managed care by the burgeoning HMO industry is that there will be a substantial cost-benefit by the use of preventive medicine. This assertion is only partly true as there are now many studies which refute this statement that everyone assumes to be correct. In spite of good information to the contrary, lawmakers continue to push for and HMOs have boasted about the inclusion of preventive services in their insurance benefit packages.

This is not to say that prevention is not a worthy health investment, but there are a large number of studies that show that preventive services are rarely cost effective. The Office of Technology Assessment (OTA) has reported that of all the preventive services they evaluated, there were only three that broke even in the end: prenatal care for the poor, newborn testing for congenital disorders (ie., phenylketonuria and hypothyroidism) and most childhood immunizations.

Preventive medicine has been the single most important driving force behind the increased longevity of Americans, mainly occurring during the past century. Public health services which protect us from crippling diseases, improved water and sewage systems, cleaner food, air and purer drugs; safer workplaces and educational programs directed toward good nutrition, proper hygiene and regular exercise have been so effective that the leading causes of death in this country are those associated with age—heart disorders, cancer and respiratory problems.

Contrasted with the obvious benefits of childhood immunization, prenatal care and newborn testing are the excessively high costs of screening for diseases such as cancer, sexually transmitted diseases and high blood pressure. These screening procedures, unless limited to high risk groups, generally cost more than treating the diseases they are trying to detect.

It seems that preventing disease is often more expensive than treating it; vaccinations and screening tests must be given to a large number of people to avert even one case of commonplace illnesses. An example would be a $10 test or shot given to 10,000 people averting maybe one case of a disease, entailing the same expense as providing $100,000 worth of treatment to one person. Also, preventive measures are not perfect and some small number of any immunized or screened group will develop the disease or sustain complications from the immunization.

Also one must consider that being protected from one disease statistically increases the chances of dying from another disease or growing older and undergoing biological decay, therefore living longer and costing more while they were dying. Considerations such as these will cause the HMO actuaries to make very hard decisions about continuing services for the elderly and the chronically ill. That we will all die is no reason that any service should not try to avoid pain and suffering, whatever the price. If the cost saving goals of the HMOs are to be met, however, they cannot afford to take chances. Their funds are not limitless and indiscriminate investment in prevention will soon deplete their coffers and they will soon be out of business. Therefore, HMOs are going to have to be exceedingly careful in weeding out those preventive services that are more exotic than helpful, and the patients in their panel are going to have to be careful and read all the fine print in their contracts. You can be sure that any successful HMO will have done its homework and done cost effectiveness studies to weed out those secondary preventive measures which will not pay off in the long run.

Primary prevention, encompassing counseling and immunizations, is usually inexpensive and whatever improvement in health it buys is usually a bargain. Exercise, diet and anti-smoking programs in the workplace have been found to reduce medical bills an average of 20%. Immunizations are also valuable, except in those diseases that are so low in incidence that the risk of side effects is greater than the odds for getting the infection. An example of this would be smallpox; a survey published in 1967 showed that the 14,000,000 vaccinations given every year caused 7 to 8 deaths and countless complications, when at the same time there were no cases of the disease for two decades.

In contrast to primary prevention, secondary measures such as most screening tests, have no effect on whether or not someone gets a disease, have false posi-

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tive and false negative rates, must be repeated often, and can be almost impossible to analyze. Consider the current quandary over cholesterol testing and treatment, the OTA reporting that even for high risk groups, cholesterol lowering programs appear to have no significant impact on overall mortality.

Similarly, the benefits of screening for prostate cancer are less than clear: the evidence collected so far indicates that there are minimal benefits. PSA tests have a higher false positive rate than the risk of getting prostate cancer; even if the positive result is correct, the microscopic tumor may never pose a problem and starting treatment may not benefit those tumors that would have progressed anyway. There's no good evidence that early detection of prostate cancer prolongs a man's life, and furthermore early detection leads to a plethora of follow-up measures, such as biopsies, prophylactic surgery, drug and radiation therapies–all of which are expensive.

Breast cancer, the second leading cause of cancer deaths among American women, consumes more health dollars than any other cancer—$6.5 billion in 1990. Screening mammography is given credit for averting 30% of breast cancer deaths among the age group 50 to 70, younger women gaining very little due to the false negative rate in denser breast tissue. The evidence to justify screening women younger than 50 for breast cancer is weak at best in that no matter what screening technologies are used, early detection would do little to lower mortality in these young women.

Making these distinctions will be critical to the development of economically rational HMO policies; the difference between liberal screening and selective screening sometimes adding up to large year-end deficits. Advocacy groups such as the American Cancer Society bear no responsibility for costs and can glibly set recommendations and parameters that are far out of bounds for the organization that will have to pay for the tests and preventive measures. Examples would be the cost savings of Pap smears done every three years rather than every year; saving one life of women older than 65 becoming seven times more expensive if done each year. How the HMO will avert the liability of unconformance with these parameters is uncertain, but physicians will most certainly be caught in between.

Physicians dealing with HMOs can expect benefit packages to be developed for the detection and treatment of all illnesses; and can also expect these packages to be strictly enforced by their quality control nurses and actuarial personnel. To date the quantifying of outcomes of medical practice is not an exact science; cost-effectiveness analysis that compares the number of years of life a procedure may save to its price is subject to criticism because of the use of different methodologies and the difficulty in placing a dollar value on an extra year of life added by screening. It is also going to be very difficult to comparison shop between very different medical services, such as whether to spend $2 million dollars on prenatal care rather than on bone marrow transplants for leukemic patients, a dilemma already faced by health officials in Oregon, with the prenatal care winning out.

These comparisons are problematic in that not everyone agrees on how much years of life are worth, most feeling that $100,000 to be too much for one year and most thinking that $25,000 is appropriate. There are no logical ways to set boundaries and different people draw different boundaries; an older person suffering from a chronic condition might not value another year as much as a young, healthy person. Because of this, interventions affecting the quality of life rather than length of life are being studied by the Office Of Disease Prevention and Health Promotion. Units such as quality-adjusted life years (QALYS), instead of just years of life saved, are combined into one measure. An extra year of perfect health would be one QALY, the value being discounted to reflect any undesired effects. How to capture quality hasn't been standardized as of yet and cost-effectiveness is to be used as a decision-making tool – but not as the justification for the decision.

HMOs are forcing physicians to serve a dualistic role: they must care for the individual patient who is sick and at the same time look out for the welfare of the health plan. These two interests are diametrically opposed and the HMO increasingly will view the sick as a burden on their panel, gradually cranking down the screws by weeding out unproductive doctors and patients with costly diagnoses. The traditional school of thought on prevention was, when in doubt, do it. This might work with one person, but consider the cost of massive screening programs and a different aspect is demanded.

From a financial point of view, HMOs will use prevention as a mode to gain market share but will have to weed out those screening services that are the least cost effective. Prevention alone can neither eliminate medical inflation nor mortality, but potentially can limit suffering and pain, and for that reason should be required to be equally available to members of all HMOs. The final test for managed care practices (HMOs, PPOs, IPAs) will be the price it is willing to pay for quality of care and just how much value it will place on quality of life, regardless of it's "bottom line"!

Birthday Calling

*by Walter C. McCoy, M.D.**

For many years birthdays meant very little for me. I do recall how depressed I felt on my 18th. Here I was 18 years old and had not even completed my undergraduate studies. I had done nothing to distinguish myself and in the early 30s things looked bleak indeed. Somehow I survived and went on to complete my ambition to be a doctor. In the first half of my practice, birthdays still meant very little. Then a very dramatic change occurred one gloomy day when Mary Wilson came in for her usual blood pressure evaluation.

Mary had obviously been crying and her eyes were sadly reddened.

"I just feel so bad," she said. "It all happened yesterday. It was my 40th birthday. All morning I stayed close to the phone hoping that someone would call. The phone remained silent. Finally, late in the afternoon it rang. My spirits soared. Someone, I thought, someone had remembered! On the other end of the line, in a dead-tired voice a man said, 'This is Elmwood Cemetery. We would like to interest you in a lot.' I replied, 'No, thank you.' and then hung up. I cried and cried and cried. It was the worst birthday I ever had."

"Let me," I said, "Wish you a belated Happy Birthday, Mary!" She smiled a very wan smile. "And Mary, " I continued, "So long as I live every year I will call you on your birthday." Mary was so pleased that I have continued this calling to the present time. Then I reasoned that if it helped a 40-year-old so much, it might benefit my other patients. I began calling all over 70. The response was so heartening that I extended it to all my patients and have kept it up even since I retired.

Birthday calling has been a true delight in my work. The patients without exception anticipate and enjoy these calls. They have told me things I never could have known about their personal relations — their worries, their jobs, their families, their money. Unreservedly they spoke of all these interests; often anecdotes and jokes were exchanged. On rare occasions, for a minor illness, I would call in a prescription. But the purpose was always just to let them know that I cared for them and wished them much happiness. I even kept up the calls when they moved far away. I must confess that these calls also enlivened by days and I always looked forward to making them.

Of course there were problems. Their phones would be busy; they were out of town; they had moved away without notifyingme; and, worst of all, occasionally I would forget. To prevent memory lapses, I made a BIRTHDAY BOOK. By my last approximation there were over 800 listed names. Unhappily, some had been crossed out due to death.

Birthday calling has done as much as anything I have done to let my patients know how much I care for them. And it has also allowed them to tell their feelings towards me. In this turbulent era of cost-containment and managed-care with the constant threat of governmental interference, to me Birthday Calling has been a real blessing.

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*Emeritus Staff, St. Vincent's Hospital, Birmingham.

Neurosurgery In Paradise

*by Thomas L. Francavilla, M.D.**

Palm trees, sunshine, a warm ocean and welcoming people are the images associated with South Florida. With this in mind I began a neurosurgery practice in what could be considered paradise. Prior to this I had entered a three-man group practice in the Philadelphia area following completion of my residency training. Philadelphia is a rather parochial city with an overabundance of academic medical centers. Although our practice was rather large, referral patterns still favored the university medical centers for patients with complex neurosurgical disorders. For a neurosurgereon with an interest in complex intracranial microsurgery there was an element of frustration.

However, the practice was established and expanding but the appealing aspect was having an academic appointment at Hahnemann University with considerable responsibility for training the neurosurgical residents. This interaction was both enjoyable and stimulating. Unfortunately internal politics pointed toward a change in the residency training program. Therefore, I turned down entering formal partnership in the practice and set my sites for the comforts and joys of sunny Florida.

Ft. Lauderdale is no longer spring-break haven for hoards of college students; the city worked hard at changing this image over 20 years ago. Now it is a city of the extremes; on the ocean side reside established wealth and 100 foot yachts, on the opposite side of the city, adjacent to the Everglades, are the newly affluent. Between these sides of the city reside the middle class and a considerable group of impoverished people. When I decided to move to Ft. Lauderdale I had visions of ocean front living with leisure time spent on the beach. However economic realities soon directed me inland. Thirty minutes of traffic and congestion lay between home and the beach. This became my first disappointment.

Practicing in South Florida is unusual in several ways. The government's involvement in health care became the paradigm for the Clinton's plan. Interestingly, many doctors preferred the government's intervention to that of managed care, which has a considerable market share of "lives" (insurance jargon for patients). For example, Humana Health was reimbursing physicians whom they did not capitate at 70% of the Medicare rate. Physicians were not concerned with increasing their income, or even staying at their present level; rather they were fearful of a significant decline in income production, a deterioration of their present quality of life. To combat managed care and their tremendous profits at the physician expense, doctors hurriedly formed networks. These networks were often integrated with a hospital system or took the form of specialty Independent Physician Associations. This deteriorating economic situation became my second major disappointment.

The medical malpractice situation in South Florida is novel. Basically the insurance rates for most of Florida are doubled when applied to this area. A neurosurgeon's $1 million/$3 million coverage was priced in the order of $180,000 annually. Were this not bad enough, many insurers would not allow this amount of coverage for the risks for a pay-out were too great. However, $250,000 of malpractice coverage per occurrence could be obtained for $110,000 annually. This situation received national attention in the 1980s when most of the area neurosurgeons refused to cover Emergency Rooms. Part of the settlement of the situation was dropping the requirement that physicians carry malpractice insurance. The economics of this explain why approximately 30% of all physicians, 60% of all surgeons and practically all neurosurgeons do not carry malpractice insurance, or have significant lapses in coverage. This "going bare" did decrease the nuisance suits brought on by the legions of attorneys in the area (one hint of this would be the 87 pages of lawyers listed in the Broward County Yellow Pages). To compound these problems, malpractice is often equated with a bad result. Should a malpractice action be taken, a bare physician would hire his own defense team, with fees generally in the order of $50,000-$100,000. If the ruling is against the doctor a payment schedule with the plaintiff would be arranged. However, in large judgments payments would be prohibitive; hence, most doctors would declare bankruptcy. While this option does not seem attractive, the consequences are not as severe as may appear for those prepared for the event as asset protection is heavily stressed in financial planning. Additionally, Florida has a Homestead law which protects one's house from bankruptcy

*Birmingham., AL.

actions, as such, doctors invest heavily in their homes. Annuities are also protected and pension plan investments are directed to this area. Needless to say the Florida Trial Lawyer Association is lobbying heavily to change the bankruptcy laws. The malpractice situation became my third major disappointment with Florida.

Despite the aforementioned disappointments, patient care in South Florida can be quite rewarding. The variety of patients cared for includes affluent transplanted northerners (who understandably often had their complex medical care undertaken in the north where there children could help care for them), the large number of working poor, the homeless (attracted by year around warm weather), remote inhabitants of the Everglades brought down to my hospital with state funds, and people from the small island countries of the Caribbean. Like all doctors I have several memorable patient encounters but, I particularly recall one baby from the Bahamas born with a low myelomeningocele, which I closed, and hydrocephalus, which I shunted. The mother takes wonderful care of her child back in their home country and becomes appropriately concerned of a failed shunt every time the child is lethargic or vomiting. Since there is no CT scanner in their country the child must be flown into Fort Lauderdale to rule out shunt failure. On one occasion this turned out to be a rather arduous method of diagnosing a missed otitis media.

The violence in Miami is well publicized in the media and Ft. Lauderdale, being part of the metropolitan area, has its share. A recent survey listed Ft. Lauderdale as having the highest per capita major crime rate in the country. It was not unusual to hear of a woman coming home and being greeted by armed burglars. My small children came home from their first day of public school with notices for the parents to sign acknowledging that it is unacceptable for children to bring knives or guns to school. They were enrolled in private school the next day. I was exposed first-hand to some of the violence of the area, managing much of the neurologic trauma in the North Broward Hospital District. Although the circumstances are unfortunate, this large patient base provided an opportunity to participate in national clinical trials for promising new treatments. On the other hand, potential malpractice suits lay with every injured patient to whom a physician is assigned under emergency conditions. This compounded my potential liability because I would not turn away complex neurologic surgical cases. At this point I read the writing on the wall: regressing incomes, a litigious practice atmosphere and excessive violence and crime. This was not the place for me to raise a family.

In deciding to relocate my practice I was in a rather fortunate position. Although my specialty is overserved in many areas, there is still considerable choice in practice locations. I came in contact with Tom Staner, a neurosurgeon in Birmingham who suggested I visit the area. Having been born in New York, educated in Boston and trained in Washington, D.C., I had several preconceptions of Alabama and initially declined his invitation. However, as I researched the area I became more curious and eventually visited. I was impressed with a progressive medical community, beautiful geography and expanding economy. More surprising to me was finding a community where friendliness and civility between people is deemed important and where a good work ethic is generally still present. An illustration of this can be seen in my postoperative lamincectomy patients: in Florida they generally wanted to be cared for and stay in the hospital as long as possible, whereas my patients here generally want to leave as soon as possible! For the most part we consider Alabama a well kept secret. We feel we have found an excellent place to practice medicine and a wonderful place to call home.

Alternatives For Addressing Financial Distress In The Healthcare Industry

*by Robert B. Rubin**
John T. Mooresmith†
*Timothy M. Lupinacci***

A. INTRODUCTION

The continuing uncertainty of congressional efforts to implement wide-spread reform in the healthcare industry increases financial pressure on healthcare providers, systems and individuals. In the constantly evolving industry, healthcare providers[1] must be aware of the proper role and function of various legal alternatives in dealing with financial distress. A healthcare provider facing increasing monetary pressures must identify the imminent financial problems, and analyze its ultimate business goals and objectives to avoid financial disaster.

Chapter 11 of the United States Bankruptcy Code addresses corporate reorganizations, and is an accepted planning device for distressed commercial and not for profit entities. Given the high cost attendant to an extended reorganization under Chapter 11, many companies and individuals seek alternatives to bankruptcy. Out-of-court workouts and pre-packaged Chapter 11 cases are often less expensive and shorten the time-frame of dealing with financial distress.

This article provides an overview of the myriad legal options available to a healthcare provider facing financial difficulties. The article will detail out-of-court workouts, pre-packaged bankruptcy, and Chapter 11 reorganization. The primary underlying theme of each of these options, however, is the necessity of identifying financial problems early and analyzing the appropriate legal action necessary through proper planning and implementation.

B. OUT-OF-COURT WORKOUTS

1. Overview.

If the principal problem facing the healthcare provider involves an inability to service its debt payments, an out-of-court workout may be a viable alternative to bankruptcy. An out-of-court workout—or more simply a "workout"—involves informal negotiations aimed at reducing the financial burdens facing the company or individual. In a workout, there is no judicial intervention, and business operations are not scrutinized by the public or by any court. Further, the healthcare provider avoids the stigma of bankruptcy that tends to erode consumer confidence. Out-of-court workouts avoid the administrative burdens and expenses inherent in a Chapter 11 case, and management stays in complete control of operations.

A workout arrangement begins with a communication from the distressed healthcare provider to its major creditors. This communication requests that the creditors attend a meeting regarding the financial conditions of the provider. During this meeting, the company's officers, attorneys and/or accountants present information to the creditors outlining the financial condition of the entity, and its plan for dealing with the financial problems. The success of an out-of-court workout often hinges on this presentation to creditors. The healthcare provider must ensure that most of its significant creditors accept certain necessary concessions, and that they retain confidence in current management. Therefore, much time and effort is typically spent preparing for the meeting with creditors.

The prospects for a successful out-of-court workout are greater when the company has unencumbered assets; that is, assets which are not already pledged as security for any debt. This enables the company to provide additional collateral to pacify significant creditors. As a fallback position, the option of Chapter 11 is available at any stage of an attempted out-of-court workout. Therefore, if significant concessions are not agreed to at the meeting with creditors, the provider can always resort to bankruptcy.

2. Advantages of Workouts.

There are many advantages to a creditor or lender coming to the table in a workout setting. First a work-

[1] The term healthcare provider is used generically in this article to refer to a business or individual engaged in business in any aspect of the healthcare industry, including hospitals, doctors or vendors.

out is usually less disruptive for the healthcare provider and its doctors, administrators, staff and patients than is resort to bankruptcy proceedings. In a workout setting, the people who currently manage and run the hospital remain in place, therefore the individuals having the most experience and knowledge about the operation of the healthcare facility continue its operations. Second, healthcare personnel have an incentive to see that the operation succeeds and therefore creditors typically like the management team running the company while the workout occurs and the financial burdens are resolved. Third, a workout provides the mechanism for a lender or creditor to keep a loan current on its book rather than writing it off as in default. Finally, a workout permits a creditor or lender at least some recovery of the funds owed rather than none at all.

It is critical for the healthcare provider in financial distress to identify its financial problems as early as possible. When the distress reaches the point that creditors have obtained judgments or are attempting to shut down the hospital, an out-of-court workout is highly unlikely.

C. PRE-PACKAGED BANKRUPTCY CASES

1. Overview.

A pre-packaged Chapter 11 is a procedure designed to conduct a largely out-of court restructuring that is subsequently consummated under the authority of a bankruptcy court. The process of a pre-packaged bankruptcy case evolves similarly to the out-of-court workout. Typically, negotiations will ensue with major creditors, the company will prepare certain disclosure documents and thereafter present a plan for voting. Prior to filing the pre-packaged case, the financially distressed healthcare provider solicits acceptances of its plan of reorganization in compliance with non-bankruptcy law governing adequacy of disclosure, or in absence of such state law, compliance with the disclosure requirements of the Bankruptcy Code. The plan must be distributed to substantially all impaired creditors and stockholders allowing reasonable time for the acceptance or rejection of the plan.

2. Advantages of Pre-packaged Plans.

The advantages of pre-packaged Chapter 11 bankruptcy are many. Since the pre-packaged plan is negotiated before the Chapter 11 case starts, it can take advantage of all the benefits available under the Bankruptcy Code without the detriments of a prolonged and expensive proceeding. Pre-packaged Chapter 11 cases save time and expense because the most time-consuming task of a Chapter 11 case, negotiating and obtaining acceptances of the plan of reorganization, is completed before filing the bankruptcy case.

A Chapter 11 plan is filed with the bankruptcy petition, thereby significantly shortening the time a Chapter 11 case remains open. For these reasons, prepackaged Chapter 11's increasingly have been utilized by debtors in addressing financial distress.

3. Disadvantages of Pre-packaged Plans.

The disadvantages of pre-packaged bankruptcy cases include that it involves extensive and time-consuming negotiations prior to the filing of the bankruptcy case, and requires a standstill with creditors during the negotiations. There is always the possibility that certain groups of creditors will withhold acceptance of the plan, and no assurance exists that confirmation will occur after the bankruptcy case is filed. The pre-packaged bankruptcy plan must comply with all applicable non-bankruptcy laws including federal securities laws.

Again, the issue of timing is critical in filing a pre-packaged bankruptcy plan. If the healthcare provider is to the point where creditors are beating down its doors, there is not time to negotiate and have adequate disclosure for a pre-packaged bankruptcy plan to work. Careful planning, however, and a reasonable analysis of a company's financial distress, will provide the pre-packaged bankruptcy plan as a viable alternative for a company's financial problems.

D. CHAPTER 11 REORGANIZATION

1. Overview.

Chapter 11 of the Bankruptcy Code sets forth the process of reorganization, and outlines what a plan of reorganization must, and can, contain. The stigma associated with bankruptcy has diminished in recent years, and therefore bankruptcy is a valid business option for the healthcare provider.

Pursuant to the Bankruptcy Code, eligibility for filing a Chapter 11 petition is broad including: individuals, partnerships, corporations, unincorporated associations or business trusts that reside or have a domicile, place of business or property in the United States. There is no requirement that the debtor be insolvent or unable to pay its debts as they mature to file a petition in bankruptcy.

2. Advantages of Chapter 11.

The advantages of filing a Chapter 11 are numerous. The filing of the bankruptcy petition operates as an automatic stay against legal action of any kind, lien enforcement and collection acts against the debtor's property. Another advantage of Chapter 11 is that it offers the debtor a "breathing spell" within which it can negotiate the restructuring of payments on pre-petition indebtedness while continuing to operate its business. Upon filing the bankruptcy petition, no debt service accrues on pre-petition debts, and no interest accrues except on oversecured debts or if the debtor is solvent.

One attractive advantage of Chapter 11 is that current management generally retains control of the company as a debtor-in-possession absent the appointment of a trustee. Once the Chapter 11 commences, the healthcare provider has the duty and obligation to conduct its business as a fiduciary in respect to its creditors.

Another "sword" of the Chapter 11 debtor is the ability to terminate or renegotiate contracts and leases whose obligations will unduly burden or threaten business of the healthcare provider. The debtor will often be able to renegotiate executory contracts upon more favorable terms because of the debtor's leverage through its ability to reject such contracts.

The debtor also has initial, exclusive control over formulating and proposing a plan of reorganization. Unless the period is extended or reduced for cause, or unless a trustee is appointed, only the debtor may file a plan within 120 days after filing its bankruptcy petition.

3. Disadvantages of Chapter 11.

Despite the numerous advantages to filing a Chapter 11, a business must balance the disadvantages to such action. Current management does face a potential loss of control and uncertainty given the bankruptcy court's equitable power to issue any order, process or judgment necessary to effect the purposes of the Bankruptcy Code. Further, the case may be converted to a liquidation under Chapter 7, or dismissed. In a Chapter 7 case, a trustee will come in wind-up the affairs of the company while liquidating its assets.

Another significant consideration is the delay and expense associated with a Chapter 11 case. The costs associated with a Chapter 11 can be enormous, and include loss of business and loss of key employees. The debtor must pay the costs of the debtor's team of attorneys, accountants and other professionals, as well as the costs of professionals retained by the unsecured creditors' committee.

4. The Chapter 11 Process.

Once the decision to file the bankruptcy case is made, the primary goal of the Chapter 11 debtor is the formulation, confirmation and consummation of a plan of reorganization. A plan of reorganization must be preceded by a disclosure statement, which contains information necessary to enable a creditor or other party-in-interest to make an informed judgment about the plan of reorganization. Solicitation for acceptance of the plan can only occur after approval of the disclosure statement. Creditors can object to the disclosure statement based on its lack of adequacy of information.

The court confirms a plan of reorganization at a confirmation hearing.

A business contemplating reorganization through the bankruptcy process must analyze numerous factors. Once an informed decision is made to file a Chapter 11 petition, the business should undertake significant pre-bankruptcy planning, if possible. This planning should include cash planning, Debtor in Possession financing planning, analyzing the timing of the filing, determining where to file the case, preparing documents to be filed early in case, developing a reorganization team including professionals and management and preparing necessary press releases.

E. CONCLUSION

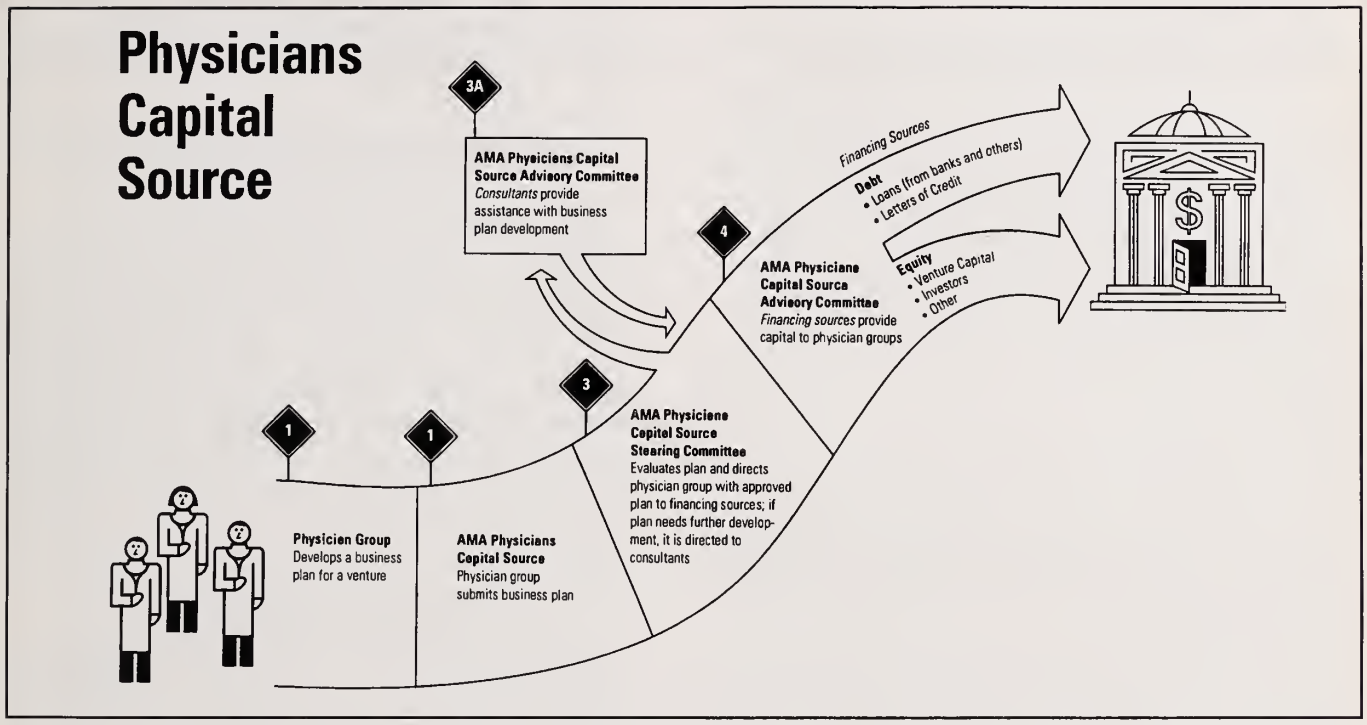
Healthcare providers facing financial difficulties have numerous legal options to address the situation. Through early detection of financial distress, the healthcare provider, whether it be a practice group, hospital, vendor or individual doctor, can take advantage of proper legal and financial planning to avoid financial disaster. By choosing the appropriate action, whether it be an out-of-court workout, a prepackaged Chapter 11 or Chapter 11 reorganization, the healthcare provider can avoid liquidation of its assets. The advantages of identifying and addressing financial problems prior to financial ruin are obvious. The ability to successfully steer through financial distress requires appropriate guidance in analyzing the many legal alternatives for restoring the financial viability of the company or individual.

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PHYSICIANS CAPITAL SOURCE



Project Overview

The American Medical Association's (AMA's) Physicians Capital Source is dedicated to helping physicians take leadership roles in the health care delivery systems that are developing across the country. Physician leadership is essential to maintain the high quality of care that is unique to the U.S. and to allow physicians to uphold their ethical obligation to put patients first.

The Project's goal is to facilitate formation of physician-led ventures by providing education and hands-on assistance to physicians who are seeking to create such ventures. **Specifically, the Project will assist physicians with the two most critical steps in the creation of a business: development of a solid business plan and identification of and access to potential financing sources.**

Business Plan Development and Review

Two documents have been created to provide physicians with a "blueprint" for business plan development. First is an extensive **"Request for Information"** (RFI) that identifies the major components of a viable business plan. Developed specifically for physicians by a team of expert financiers, business consultants and the AMA, the RFI contains the strategic and operational issues that physicians must confront when building a new business — and that financiers consider vitally important in evaluating such ventures.

The RFI is explained on a question-by-question basis in a concise publication called ***Developing a Managed Care Business Plan: A Physician 's Guide.*** This guide, available for a modest fee, will enable physicians to gain a significant head start in planning and to reduce significantly the professional fees typically required for business plan development.

Physicians submit completed business plans to the AMA for evaluation by the **Physicians Capital Source Steering Committee**, which is composed of AMA representatives, financiers and business consultants. Based on a summary review, the Committee's financing and business members determine whether the plan should proceed to financing or whether it needs more development.

If a business plan needs further development, the physician will be contacted and specific areas of plan weakness will be identified. The physician will be referred to a member of the **Physicians Capital Source Advisory Committee** — a national panel of

managed care experts, legal advisors, business consultants and financiers who support the Project's goals.

The Steering Committee will select an Advisory Committee member who has expertise in the particular type of proposed venture (e.g., integrated delivery systems, physician networks, group practices, etc.). The physician may retain the recommended consultant, or any other, to bolster the plan and submit the revised plan for review.

Referral for Financing

When the Steering Committee determines that a business plan is ready for funding, it will refer the plan to a financing member of the Advisory Committee. **Physicians will only be referred to the types of financiers who are most likely to meet the objectives defined in their business plan and who are acceptable to the physicians**, whether venture capital firms, commercial banks or investment banks. If that member is unable or unwilling to finance the deal, other financing sources will be pursued.

Criteria for Participation

The Project is open to all physicians who have developed **"physician-friendly plans" as defined in the attached Statement of Operating Principles and Guidelines.**

Physicians who are not AMA members pay an application fee that covers administration of the Project and the initial reviews of the Steering Committee and the Advisory Committee; the fee is waived for AMA members. Subsequent consultations by Advisory Committee members are negotiated privately with the physician.

Advisory Committee members pay modest fees to the AMA upon successful financing, or when retained for business plan development, to offset the Project's direct expenses.

A substantial practice development effort and pursuit of funding may require a significant investment. Capital acquisition often involves fees, pledged assets and\or equity participation, which should be factored into financial planning.

Support for Physicians Transitioning to Managed Care

Neither the AMA, acting through Physicians Capital Source, nor the Steering Committee can guarantee that a particular venture will be funded or will ultimately succeed. **While there are never guarantees in any line of business, Physicians Capital Source provides a support system** for physicians making a transition to a managed care environment. The process is designed to be efficient, minimizing false starts, exorbitant investment in impractical business plans and inappropriate approaches to capital sources.

For More Information

For more information on Physicians Capital Source, or the application forms, call the AMA's Managed Care Help Line at 800-AMA-1066, press 2.

Mission Statement for Physicians Capital Source Advisory Committee Members

Physicians Capital Source Advisory Committee members shall make every effort to accomplish the following goals:

Support the aspirations of physician participants who are developing new practice structures in a changing environment.

Make appropriate contacts and seek out capital commitments with financing entities on behalf of such physicians.

Mobilize resources to support effective strategy development for participants.

Assist participants in refining their business plans and guiding them toward appropriate sources of financing.

Provide objective, analytical evaluations of submitted business plans. Deliver criticism in a constructive and professional manner.

Support and abide by the Project's Statement of Operating Principles and Guidelines.

Expectations for Physicians Capital Source Advisory Committee Members

Members of the Physicians Capital Source Advisory Committee (Advisory Committee) members are requested to observe the following guidelines to insure efficient Project operation.

1. The Project Steering Committee will screen submitted plans and refer them to Advisory Committee members based on appropriateness of fit and area of interest. The more clearly you identify the types and sizes of projects you are most interested in, the more efficient and timely our referral process will be.
2. A primary objective of the Advisory Committee process is to strengthen physicians' plans such that they qualify for and ultimately receive funding. Take all steps necessary to achieve this objective.
3. Establish initial contact with the submitter within 72 hours after receipt of the business plan. If you have not had sufficient time to review the plan, advise the submitter accordingly and provide a date by which the review will be complete. Generally, the first meaningful conversation with the submitter should occur within 10 days of receipt of their plan.
 a. Recognize that many submitters are venturing into new territory and that your analysis and counsel represent a crucial step in the process. Patience and sensitivity to the significant changes they are experiencing will do much to allay anxiety.
4. Provide the initial consultation, largely involving additional clarification and input, on a complimentary basis. If the submitter and you determine that there is a basis for a professional engagement to improve the business plan, a consulting agreement at normal billing rates is appropriate.
5. If you represent a financing source, plans will be submitted to you after screening by either the Project Steering Committee or another Advisory Committee member. In such cases, the business plan will be ready for immediate financing consideration. Contact the submitter and determine whether you can assist with the necessary financing.
6. If the plan is not in your area of interest or you cannot pursue it for any reason, immediately advise Dr. Steve Altman, Project Manager, at 818 585-8400, and return the plan. If you make another referral, please advise the Project Manager as well.

If you are interested in the plan, notify Dr. Altman as soon as you make the initial contact with the submitter. Dr. Altman will make arrangements for subsequent progress reports, and if necessary, an introduction to a potential financing source. This information is needed for tracking and reporting to the AMA.

Maintain business plans, trade secrets and other proprietary information contained in all plans in strictest confidence.

The AMA, as a not-for-profit membership association, is not in the business of providing business or legal advice to individual physicians. The AMA does not assume responsibility for advice or services rendered by Advisory Committee members.

Physicians Capital Source Advisory Committee

The Physicians Capital Source (PCS) Advisory Committee is a national panel composed primarily of consultants who develop health care ventures and entities that finance these ventures. Its 161 members also include related health care entities, such as Blue Cross plans, medical clinics, a health maintenance organization, foundations and experts in information technology.

The Advisory Committee represents 13 states and the District of Columbia. California has 31 representatives; Illinois has 7; New York has 5; Texas has 3; Connecticut, the District of Columbia, Indiana, New Jersey and Ohio each have 2; Arizona, Georgia, North Carolina, Massachusetts and Pennsylvania each have 1.

Advisory Committee members are selected on the basis of demonstrated expertise, a national reputation, a commitment to development of physician-led ventures and agree to support the goals of Physicians Capital Source. The scope of the Advisory Committee is continually being expanded, both geographically and by area of expertise, to offer applicants a broad base of professional support.

PCS Advisory Committee members include the following:

- **Investment Banking Firms** — 6 investment banking firms;
- **Venture Capital Firms** — 11 venture capital firms;
- **Commercial Banks** — 3 commercial banks, including a bank that has over 90% of its business devoted to health care ventures, including many physician ventures;
- **Asset-Based Financing Firms** — 2 asset-based financing firms;
- **MIS\Information Technology Firms** — 2 management information systems\information technology firms;
- **Health Plans** — 4 health plans (clinics and HMOs);
- **Consultants** — 21 consultants, including experts in formation of specialty networks (e.g., ophthalmology carve-out networks), surgicenters, independent practice associations and information systems;
- **Legal Counsel** — 8 attorneys; and
- **Other** — 1 real estate development firm.



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AIR FORCE

American Medical Association Physicians Capital Source Operating Principles and Guidelines

Operating Principles and Guidelines Physicians Capital Source operates under the philosophical and ethical principles of the American Medical Association (AMA). The Project's primary goal is to assist physicians to obtain access to the financing necessary to implement new physician-directed practice structures within a managed care environment. All Project participants should be aware of and accept the following Operating Principles and Guidelines.

Statement of Principles

In June 1994 the AMA's Council on Ethical and Judicial Affairs issued recommendations addressing "Ethical Issues in Managed Care." The essence of these recommendations, which were adopted by the AMA House of Delegates, follow.

1. The duty of patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the system of health care delivery in which physicians practice. Physicians must continue to place the interests of their patients first.
2. When managed care plans restrict the care that physicians may provide, the following principles should be followed.
 a. Any broad allocation guidelines that restrict care and choices beyond the normal cost/benefit judgments physicians routinely make should be established at a policy making level so that individual physicians are not asked to engage in ad hoc bedside rationing.
 b. Physicians must advocate for any care they believe will materially benefit their patients.
 c. Physicians should be given an active role in allocation processes and should advocate for guidelines that are sensitive to differences among patients. Managed care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful, ongoing input into the plan's development of allocation guidelines.
 d. Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care.
 e. Managed care plans must adhere to the requirement of informed consent, assuring patients full disclosure of material information, including limitations or restrictions on the benefits package.
 f. Physicians should continue to promote full disclosure of treatment options to patients, even if the managed care plan does not cover certain options.
 g. Physicians should only participate in plans that encourage or require care that meets or exceeds minimum professional standards.
3. Financial incentives to physicians are permissible only if they promote the cost-effective delivery of health care and not the withholding of medically necessary care. Financial incentives should be based on quality of care, fully disclosed to patients and calculated according to the performance of a sizable group of physicians rather than on an individual basis.
4. Patients have an individual responsibility to be aware of the benefits and limitations of their health care coverage.

In addition to the recommendations described above, AMA policy supports principles which affirm the physician's professional role and stature. Among them are:

- Physicians should receive notice and an opportunity to respond before any adverse actions are taken against them.
- Physicians should not be subject to unilateral amendment of contracts.
- Physicians should receive actuarial and other information necessary to assess managed care plan performance.
- Physicians are entitled to return of withholds unless the withholds are required to maintain plan solvency.

Operating Guidelines

1. The Project will accept for review all proposed structures submitted by physicians.
2. Physician plans should be shaped in accordance with the ethical principles discussed above.
3. The Project encourages physician plans that are designed to be competitive within the region they serve and that demonstrate high value to patients, plan participants and investors. These plans will

ultimately prove to be the most successful in the marketplace.

4. The Project encourages the submission of "physician-friendly" health plans, which typically have the following characteristics:
 a. Physicians have significant policy making participation in regard to all aspects of the plan's operation. Physicians serve a significant role (usually at least 50%) on the governing board and on all committees.
 b. Plan governance recognizes physicians' primary role in medical decision-making, and physicians control utilization review and medical management processes.
 c. Plans are philosophically dedicated to maximizing the percentage of premium spent on the delivery of health care and minimizing the percentage spent on administration and overhead.
 d. There are shared investments and risk that reflect the talent of the parties to the enterprise.
 e. relationships with employers and other contracted groups are negotiated in the best interests of future patients.
5. All members of the Project, including review teams and committee members, will maintain information about submitted plans in strict confidence.
6. The Project is, by necessity, market driven, seeking to promote physician practice successes while recognizing new competitive, regulatory and structural issues. Consequently, plans submitted for review must meet the tests of normal business scrutiny and economic viability to receive funding.
7. The AMA has undertaken the Project to facilitate financing of physician-directed managed care ventures, thus enabling physicians to control their professional destinies. Just as in any business, there are no guarantees that a given project will receive funding or will ultimately succeed.

Physicians Capital Source Sponsors

Coastal Healthcare Group, Inc, based in Durham, North Carolina, is the one of the largest medical group management company in the country. Coastal provides health care and administrative services to health care providers. Coastal works with hospital based, community-based, and alternate-site physician practices.

Coastal was founded in 1977 to assist hospitals in staffing their emergency departments. Since then, the company has expanded its services to include obstetrics, gynecology, pediatrics and anesthesiology. Coastal operates 27 primary care clinics and an integrated health care delivery network that provides care to health maintenance organization (HMO) enrollees. Coastal's five major subsidiaries include: Coastal Physicians Contract Services Group, Inc.; Coastal Government Services Management Group, Inc.; Healthcare Business Resources, Inc.; Alternate Site Healthcare Group, Inc.; and Coastal Managed Healthcare, Inc.

Pacific Physician Services, Inc. (PPSI), provides management systems and services, non-physician health care personnel and facilities and equipment to affiliated medical organizations, independent practice associations and physician groups in Arizona, California and Nevada. The affiliated medical organizations employ physicians and contract with physicians, professional medical corporations and HMOs. In addition, PPSI's affiliate, Northwest Emergency Physicians, is the largest provider of emergency physician specialists and management services to hospitals in the Pacific Northwest.

PPSI provides comprehensive prepaid health care to more than 282,000 enrollees in 15 HMOs through an outpatient network of 46 multi-specialty medical centers and a full service community hospital (located in Montclair, California) owned by PPSI.

The Associated Group is a network of insurance and financial services companies. Based in Indianapolis, its products include health insurance, managed health care, life insurance, property and casualty insurance, insurance brokerage, government program administration and financial services. The Associated Group is one of the largest Medicare contractors in the country.

The Associated Group conducts business through six principal subsidiaries: Acordia, a network of insurance brokerage and administration companies; Anthem Financial l, a financial services holding company whose subsidiaries provide retail brokerage, corporate, and municipal finance services; AdminaStar, a data resource and management company; Anthem Health, which underwrites individual and group life insurance, develops and maintains health care

provider networks and managed health care products, and owns HMOs; Anthem P&C Holdings, which is responsible for property and casualty underwriting and marketing; and Southeastern Group, which provides health care and related products, including Blue Cross and Blue Shield products.

Johnson & Johnson Health Care System, Inc. (JJHCS), provides acute care and managed care customers one interface to the fill spectrum of Johnson & Johnson products and services. JJHCS is responsible for all contracting and account management with large customers, including managed care organizations, large hospitals, pharmacy benefits managers, integrated health systems, government and employers. It coordinates the consumer, diagnostic, surgical and pharmaceutical expertise of Johnson & Johnson to emphasize wellness, provide early diagnosis, deliver cost-effective treatment and encourage health maintenance.

JJHCS engages in risk-sharing with customers and also sells health management services, which include anything from developing clinical protocols to improving management of a hospital's catheterization lab. JJHCS' products include the broad breadth of Johnson & Johnson — from over the-counter pharmaceuticals to medical/surgical products to the prescription drugs dispensed in the retail and hospital pharmacy. In addition, JJHCS has a Health Management Division offering expertise in health management services and wellness.

Medimetrix Group, a consulting company based in Cleveland and Denver, provides clients with a thorough understanding of the marketplace and information about the regulatory, structural, financial, operational, negotiating, marketing, and management support needed to make new and existing enterprises more successful. Medimetrix Group is comprised of four divisions: Medimetrix Consulting Division, which builds, rebuilds, and re-engineers all types of physician organizations and integrated delivery systems; Unison Marketing & Communication Division, which provides full service marketing strategy, advertising and public relations; Tempus Management Division, which provides experienced interim management for start-up and transitioning health care businesses and executive recruiting for permanent management; and Unison Syndications Division, which syndicates marketing programs.

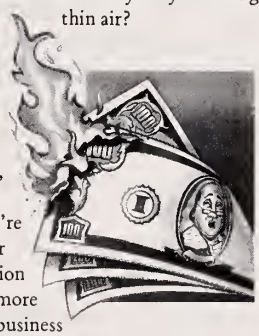
Medimetrix clients include hospitals, health systems, provider networks, medical groups, HMOs, Blue Cross organizations, insurers, employers, PPOs, third party administrators, investors, and government agencies.

Unihealth, founded in 1988 through the merger of two nonprofit health care systems, is one of the largest concentrations of healthcare resources found in any single metropolitan area. Consisting of more than 13,000 employees, 5,000 physicians, 2,000 volunteers and affiliated health plans, Unihealth is based in Los Angeles and provides service to the metropolitan area and surrounding Southern California.

Unihealth consists of a number of components in addition to its six medical groups and nine medical centers, including, among others: the Unihealth Foundation, which sponsors health fairs, community support groups, wellness programs and health screenings, provides post-earthquake and other disaster emergency relief assistance and has spearheaded an immunization program for children in Los Angeles and Orange Counties; a Professional Services Division, which provides mechanisms for physician affiliation through multiple models that offer maximum flexibility; CareAmerica Health Plans, Unihealth's HMO product, with total enrollment exceeding 200,000, and CliniShare, providing pre- and post-hospitalization technologies and services.

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Summary of Funding Requests

Following is an overview of thirteen projects the AMA's Physicians Capital Source (PCS) program has received to date:

- **Ambulatory Surgicenter** **Cost: $750,000 to $1,000,000**

This proposal is for the renovation of an existing space into an outpatient surgicenter with two operating rooms and one procedure room. The purpose is to provide a cost-effective alternative to hospital outpatient surgeries. Financing would ideally consist of a long-term loan, an equipment loan, and a line of credit.

- **Multispecialty Physician Network** **Cost: $2,000,000**

This non-exclusive IPA network is located in a low-penetration managed care market (less than 10 percent). It is expected that this network will contract with self-insured employers, HMOs, and third-party payors. Funds are needed to purchase an information system that will provide claims processing and data collection; add physicians to the network; hire staff; and conduct a marketing campaign. Primary care physicians in this network will be compensated on a capitated basis. At least initially, specialists will be paid on a discounted fee-for-service basis.

- **Primary Care Physician Network** **Cost: Up to $5,000,000**

Funds are needed to purchase an information system for this IPA network, which will "partner" with an insurance company or third-party administrator for administrative and risk services. The IPA will provide members with group purchasing, an information system, outcomes analysis, and practice management. All aspects of practice management will be centralized in the network.

- **Physician Network/Management Services Organization** **Cost: $800,000 to $900,000**

This county medical society-sponsored network is designed to meet the varying needs of physicians, who will be able to participate by purchasing some or all of the administrative services offered by the medical services organization. In addition, participants may either participate in the network or have their practices fully integrated into the network.

- **Vertically Integrated Delivery System** **Cost: $10,000,000**

A group of related companies (including companies providing insurance claims processing, insurance, home health care, provision of medical care, utilization review, and contracting functions) already provides all the necessary services to accommodate the needs of physicians in the system and the employers with whom the system contracts. This group desires to expand its organization to other parts of the state and, ultimately, to other states through a joint venture or franchising arrangement with physicians in other states. Funds will be used for expenses related to expansion, marketing, and consumer education.

- **Clinical Practice/Accounting Information System** **Cost: $1,000,000**

This project focuses on the development and marketing of an electronic device physicians and staff can use for data entry and retrieval of clinical and administrative information.

- **Health Maintenance Organization/ Independent Practice Association** **Cost: $10,000,000**

This state medical society-sponsored managed care organization (MCO) is forming an HMO which will contract with an IPA of physician providers. All medical doctors and doctors of osteopathy who are members of their respective state professional societies have been invited to become shareholders in the MCO and, subject to satisfying the MCO's credentialing standards, to join the IPA. Initially, the IPA will pay specialists on a fee-withhold basis; primary care physicians may elect payment on a capitated basis. Marketing will be performed by the MCO; administrative and management services will be provided on a contractual basis by a third party.

- **Medical Office & Treatment Facility** **Cost: $3,000,000**

This proposal is for the construction of a medical office and treatment facility for four physicians. Mortgage financing would cover 80% - 85% of the costs, with the remainder consisting of an equity investment by the physicians.

• Primary Care Clinics **Cost: $500,000**

Funds are needed for the creation of the first in a series of clinics designed to provide comprehensive primary care services to the targeted population. Clinic services would be integrated with preventive programs and home health care.

• Statewide Physician Network **Cost: Unknown**

This nonexclusive network is made up of a number of separate hospitals, medical staffs and physician organizations. Physicians are credentialed individually and are the owners. A partner is needed to assist this group in defining its products and conducting marketing.

• Equipment Leasing Company **Cost: $800,000**

Funds are needed for the start-up of a medical equipment leasing company that will offer replacement parts and servicing of equipment. The project is designed to reduce physicians' need to invest large amounts of capital in equipment acquisition.

• Software/Hardware Information System **Cost: $2,000,000**

This project involves development of an integrated software and hardware system that would quantify and monitor health care receivables for financial structuring purposes and provide portable, up-to-date, medical records.

• Information System **Cost: $500,000**

This proposal involves development of a software system with components that provide credentialing, utilization and quality management information and review.

As of April 13, 1995, other projects that have been submitted to PCS include: a county medical society sponsored provider network, and office automation software.

Overview of Projects Submitted for Funding

- 18 projects submitted to date
- 1 project complete (provided advice on financing of nephrology clinic)
- 17 active projects in 11 states
- 8 primary care sponsored
- 9 special care sponsored
- most projects involve or are sponsored by AMA members
- amount of funding sought (per project): $500,000 - $5,000,000

PRIMARY CARE BUSINESS PLANS

- 1 multispecialty group project
- 1 comprehensive primary care clinic
- 6 network formation projects
 - 3 IPA expansions
 - 3 IPA start-ups)
 - all are medical society-sponsored (one state, two county)
 - 1 of these also has an MSO
- 1 joint venture network (with an MSO in 6 states)

SPECIALTY CARE BUSINESS PLANS

- 1 multispecialty group IPA project
- 1 construction project
- 5 MIS projects (developing software applications)
- 1 medical device development project 1 start-up of equipment leasing and service company



Usha Bhuta
A-MASA President

Inaugural Speech*

Seventeen years ago while I was deep frying vegetables in my kitchen I saw a Western Union vehicle stop in front of my door. Panicked, I ran out to receive the telegram, and locked myself out of my house! I ran to my neighbor's and called the hospital: "Operator, please page my husband and tell him to come and unlock the door, because I'm afraid our house will catch on fire."

I waited awhile, but my husband didn't come home. Meanwhile, our house caught fire. Hurriedly, I called the fire department; then I called the hospital again, "Operator, tell my husband not to come home because the house is already on fire, and the fire department will help me."

Within a few minutes I saw fire trucks, a police car, and behind them, my husband's car.

Ish asked, "Why didn't you tell the operator that it was an emergency to begin with?"

My reply was, "I thought that our house on fire was an emergency."

Ish countered, "You should have called me STAT on the first call."

I said, "But I was not dying."

Then I realized that my first call had been taken as a consult.

The point I am making is that our spouses know only the language of medicine, yet they need a different language to protect their rights in today's changing world. Along with change, our spouses face challenges from legislators, insurance companies, trial lawyers, patients, and within their own families. They need us, their spouses, to speak this societal language and be their voice in the larger world.

It is with great pleasure, pride and confidence that I accept this office of President. I am thrilled to be the first foreign medical graduate's spouse to receive the highest honor bestowed by the Alliance to the Medical Association of the State of Alabama.

Yes! you have made history today, recognizing that the structure of American society has changed and the organizations of yesterday need to embrace that change today. Physicians today come from many different nations, religions, cultures, and races. Yet they all have one thing in common their noble profession of healing the sick. Let us stengthen ourselves with our diversity.

We are no longer merely doctors' wives. We even changed our name for the third time last year. For 72 years our leaders have worked hard to give us a strong foundation. I will use all the skills I have learned to make it stronger.

Among my skills and my teachers are:

my husband (PATIENCE) – when he calls to tell me his is on his way home, I never know just which way he'll take, and I reheat dinner for hours!

my two tennis playing daughters (BUDGETING TIME and SMILING IN THE FACE OF DEFEAT) – I balanced my checkbooks, worked on my taxes, wrote checks, and encouraged my children while my hair turned gray sitting on the bleachers under the hot sun!

my 16-year-old son (INDEPENDENCE) – he wants me to have my own life and leave his to him!

I also have the great help of computers, fax machines, a car phone, and Frankie.

So, shall I make promises for next year? Promises are like snowballs—easy to make and hard to keep. I would rather set some goals, because without them we will

*April 28, 1995.

never know where to go.

Our 1995-96 goals are:

1) A 5% increase in membership – no number no thunder!
2) Organize a new Alliance in each of four districts. We still have about 37 counties where Alliance has not been introduced.
3) Support our National Health project SAVE (Save America's Violence Everywhere). Work toward a joint project with MASA.
4) Continue efforts to raise funds for AMA-ERF. These funds are a silver lining for those medical students who get hit by financial troubles in the middle of their careers.
5) Support MASA with legislative issues and health related issues.
6) Invite diversity.

All the new Board members and I set these goals. Don't you agree they are realistic and attainable? Meeting these goals is the responsibility of you, the individual member, and we, the officers.

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INFORMATION FOR AUTHORS CONCERNING MANUSCRIPTS

Manuscripts from member physicians should be typewritten, double spaced on white paper 1-1/2 x 11 inches with adequate margins. Two copies should be submitted. Authority for approval of all contributions rests with the Editor. *Alabama Medicine* reserves the right to edit any material submitted. The publishers accept no responsibility for opinions expressed by contributors.

Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month – day of month if weekly – and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook / Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E.B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International,* Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

Illustrations: Illustrations should be numbered consecutively and indicated in the text. The number, indication of the top, and the author's name should be attached to the back of each illustration. Legend should be typed, numbered, and attached to each illustration. Photographs should be clear and distinct; drawings should be made in black ink on white paper. For photographs, glossy prints are preferred.

Communications should be addressed by *Alabama Medicine*, The Medical Association of the State of Alabama, P.O. Box 1900, Montgomery, Alabama 36102-1900. Telephone (334) 263-6441, or (toll free in Alabama) 1-800-239-MASA.

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Ashland, Alabama
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Annual ED Visits: 7,500
Needs: Full-time

Monroe County Hospital
Monroeville, Alabama
94 Bed Facility
Annual ED Visits: 12,500
Needs: Full-time

Jackson County Hospital
Scottsboro, Alabama
170 Bed Facility
Annual ED Visits: 17,000
Needs: Full-time, part-time

Russell Hospital
Alexander City, Alabama
100 Bed Facility
Annual ED Visits: 13,000
Needs: Part-time

Mississippi

Parkview Regional Med. Center
Vicksburg, Mississippi
231 Bed Facility
Annual ED Visits: 15,000
Needs: Full-time, part-time

Montfort Jones Memorial Hospital
Kosciusko, Mississippi
76 Bed Facility
Annual ED Visits: 8,000
Needs: Full-time, part-time

BMH - Union County Hospital
New Albany, Mississippi
153 Bed Facility
Annual ED Visits: 18,000
Needs: Full-time

BMH - North Mississippi
Oxford, Mississippi
150 Bed Facility
Annual ED Visits: 15,000
Needs: Full-time, part-time

Gilmore Memorial Hospital
Amory, Mississippi
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Annual ED Visits: 12,000
Needs: Full-time

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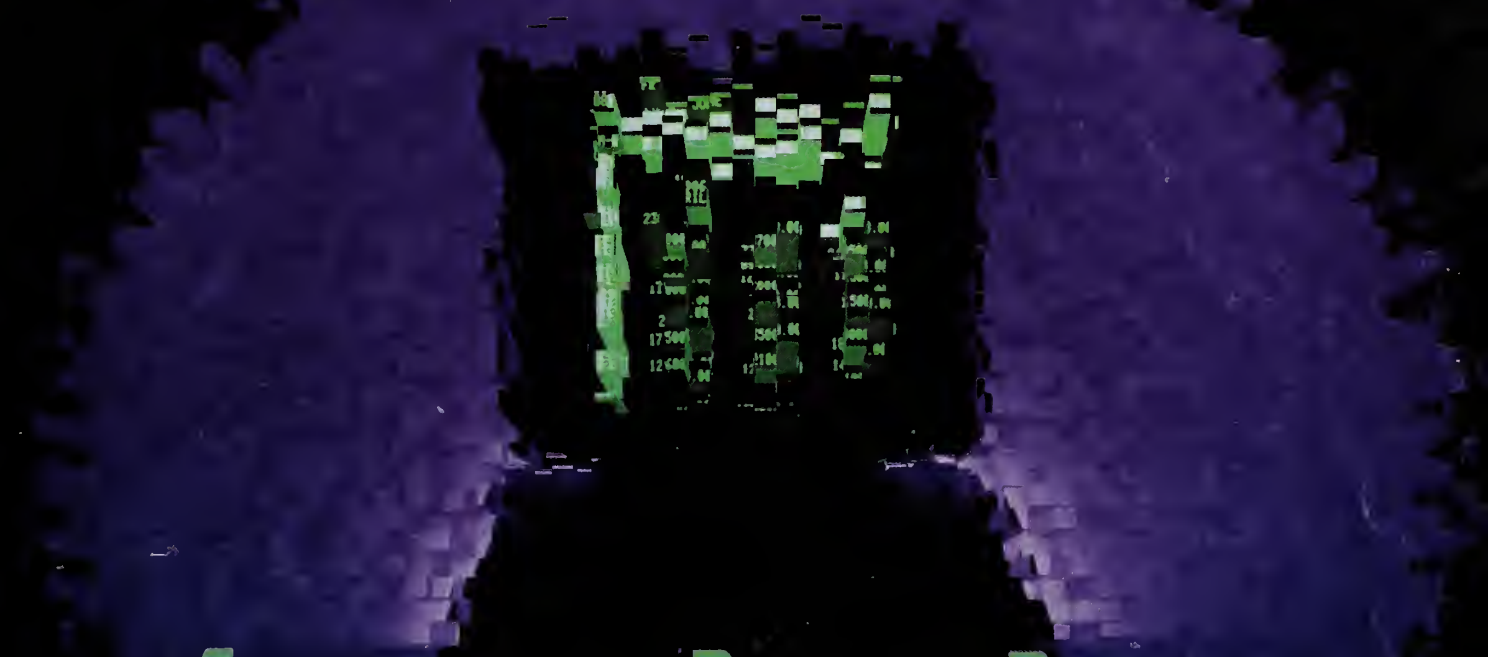
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-Robert H. Story, M.D.

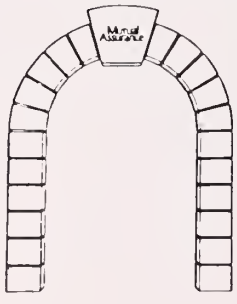
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S. Lon Conner
Executive Director, MASA

Managed Care or Mangled Care?

Crackling through the results from the recent survey of Alabama physicians was your Mayday call for more information about managed care. The Managed Care Workshops announced for July (The Alabama M.D., June 22, p. 1) by MASA Education Director George D Oetting, Ed.D., was a direct response to that demand. And you can be assured that other offerings will follow.

First of all, let's define terms. What is managed care? The spectrum is fairly broad, varying all the way from staff model HMOs (viz., Kaiser-Permanente) at the one extreme to fee-for-service indemnity plans on the other when these are accompanied by contractual arrangements with physicians, attempts at cost constraints, and fee schedules. The AMA has defined managed care as:

".... systems or techniques that are used to affect access to and control payment for health care services. Managed care techniques most often include one or more of the following:

• prior, concurrent, and retrospective review of the medical necessity and appropriateness of services and/or site of services;

• contracts with selected health care professionals or providers;

• financial incentives or disincentives related to the use of specific providers, services, or service sites;

• controlled access to and coordination of services by a case manager and

• payer efforts to identify treatment alternatives and modify benefit restrictions for high cost patients (i.e., high cost case management)."

Some economists believe that managed care is not destined to be a permanent solution for the health care cost crunch but is a transitional approach to something further down the pike – exactly what, no one can predict with any authority. Although corporate purchasers of health care appear to be reasonably content with the "savings" so far, critics say these may not be sustainable.

Moreover, some say, they may not prove to be long-term savings at all, if rationed care early on merely defers care until such time as an illness fulminates into a much graver condition, necessitating far more costly intervention and at considerably greater social impact – that is, in terms of the quality of life of patients victimized by such disguised rationing.

One of the most pungent commentaries I have seen on managed care came from Miguel A. Faria, Jr., M.D., Editor of the *Journal* of the Georgia Medical Association. Writing in the April issue, Dr. Faria cites the analysis of a Swiss philosopher, Professor Ernest Truffer, who says the managed care movement is forcing U.S. physicians to practice what he calls a *veterinary ethic*. This ethic, Dr. Faria* writes,

"... rejects the traditional medical ethic requiring a physician to care for his/her patient according to the patient's specific medical requirements, in favor of a new ethic which consists of caring for the patient as if he/she were a sick animal, not in accordance with its specific medical need, but according to the wishes of its master or owner - the person or entity responsible for paying the medical bills....

"For the first time in the history of medicine," Dr. Faria continues, "physicians are being coaxed or coerced, whatever the individual case might be, to ration health care by restricting their patient's access to specialists or expensive treatments – that is, involuntary rationing for the sake of cost containment and to make the HMOs, for which they work, more efficient and profitable.

"Today, physicians are subject to so-called cost-effective analysis and economic credentialing. This is a methodology by which hospitals and health care networks (particularly HMOs) use utilization review data about physician medical practices, not to determine quality but to monitor financial impact.

"Physicians who have not been cost-effective – that is, they have not been stringent in their restrictions, or who treat the sickest and most difficult cases and thereby incur the most costs in their communities – may have not only their bonuses withheld at the end of the year, but also could even lose their membership status in hospitals or health care networks when they apply for new, additional, or renewal of clinical staff privileges. Major health care networks are acting in collusion with government bureaucrats and policymakers to impose managed competition and to change the time-honored ethics of the medical profession...."

Mergers and acquisitions in the big networks seem to suggest that the eventual goal is a few mega-corporations owning or substantially controlling the whole nine yards. This trend, we are assured by the networks, would accomplish the ultimate economies of scale.

For a comment on this notion, I turn to the latest work by Alvin and Heidi Toffler, authors of the 1980s best sellers, *Future Shock* and *The Third Wave.* This year's small paperback – *Creating a New Civilization, The Politics of the Third Wave* – is required reading in Washington because it is No. 1 on House Speaker Newt Gingrich's famous list.

In fact, Gingrich wrote the foreword. (Let it be noted here, however, that the Tofflers, although friends of Gingrich for many years, strongly and vociferously disagree with the Speaker on some major points of policy evolution.) Here are the Tofflers on scale:

"...economies of scale are frequently outweighed by diseconomies of complexity. The more complicated the firm, the more the left hand can't anticipate what the right hand will do next. Things fall through the cracks. Problems proliferate that may outweigh any of the presumed benefits of sheer mass. The old idea that bigger is necessarily better is increasingly outmoded." (Emphasis supplied.)

In fact, the Tofflers say, the trend is in the opposite direction here in the economic realities of the Third Wave. Small businesses are multiplying. Big businesses are getting smaller:

"IBM with 370,000 employees is being pecked to death by small manufacturers around the world. To survive, it lays off many workers and splits itself into 13 different – smaller – business units."

If big were always better, then obviously the federal government could run everything better and cheaper. Does anyone, anywhere, really believe that?

In another section, the Tofflers discuss how it used to be with human labor, during the late Second Wave, when this country was driven by the economy of heavy industry, the so-called smokestack economy. In those days, muscle power was in demand but it was "fungible." That is, a low-skilled worker who quit or was fired could be replaced quickly and with little cost.

"By contrast, the rising level of skills required in the Third Wave economy make finding the right person with the right skills harder and more costly."

Reading this, I was moved to think that while that was certainly true in medicine in the immediate past, the big managed care goliaths are treating some highly skilled physician labor as if it were fungible – that is, easily replaceable – muscle power.

As long as the restricted market they are creating seems to create a surplus among such specialists, the mega-networks may appear to have leverage over those in their employ – "Either ration as we tell you or out you go."

But what happens to that leverage when the putative surpluses vanish, as seems likely, since no condition of the kind can be expected to be permanent?

I'll have more to say on this subject as I learn more about it.

**Dr. Faria, Clinical Professor of Surgery (Neurosurgery) and Adjunct Professor of Medical History at Mercer University School of Medicine, is the author of Vandals at the Gates of Medicine, a massive work of scholarship that took him almost five years to write. In it he goes back to the very beginnings of medicine to illustrate parallels between historic mistakes by rulers then and the current predicament of medicine here in the last decade of the 20th Century. For example, ancient Rome was rent by the politics of envy; civil wars were fought when demagogues used the language of today – "soaking the rich and greedy providers and price gouging." After Rome was transformed into a welfare state by the Emperor Diacletian, the state collapsed. "Doctors could no longer follow the ethics of Hippocrates and Galen that put the patient first." I highly recommend Vandals at the Gates: 403 pages, hardbound, $41.95; Hacienda Publishing, Inc., PO Box 13648, Macon, Georgia 31208; phone (800) 757-9873;* fax (912) 757-9725.

PRESIDENT'S PAGE



C. Neal Canup, M.D.
President, MASA

An Industry of Talk

Paradigm, archetype, vision, mission, strategy, performance, leverage, commitment, optimization, quality improvement, linear and nonlinear thought, etc., etc., etc.

There is a large (getting larger) industry that talks. Every seminar I go to has a Ph.D. or an Ed.D. who has a company to advise, teach, consult, and explain to us what we are doing. They not only tell us what we are doing; they also tell us how we are doing; how we are doing it wrong; how we can do it correctly; how to create a new system; how to create and change a process; how to understand the process; and how to evaluate it all.

What does it all mean? Or better still, what is its MISSION? My opinion (not researched) is when a society changes from producing products to supplying services, it loses many of its points of reference (anchors); or, another way of saying the same thing would be – the end points, the finish line, the guideposts are moving and elusive. So, what is the mission? To make us better managers, make us more productive, make us more profits? I confess, I don't know what their mission is other than talking for pay. My opinion (not researched) is with the new system of thought and management we aren't solving any problems; we are only learning a new way of talking about the same old problems. What are the problems? Worldwide competition, changing from producing products to services, automation, computerization.

Under the new system of management do workers (our employees) look forward to work? Are they more secure? Are they happier? My observation is that they aren't. So! What is all of this talk about? Words. Where does this article end? Here. There are occasions when the best response to a lot of these words is simply: BS.

Education in Preventing Sexual Misconduct in Alabama

by Gerald L. Summer, M.D.
Medical Director, Physicians Recovery Network

Professional boundaries are the limits of a fiduciary relationship in which a patent entrusts her or his welfare to a physician to whom a fee is paid for the privilege of a service.[1] Boundaries imply professional distance and respect, which includes refraining from sexual involvement with patients. The subject of sexual violations and allegations of sexual misconduct has received a great deal of recent attention in the medical literature and the news media in Alabama among other states, in Canada, and in New Zealand.[2] With social expectations and clinical practice changing so rapidly, many physicians are uncertain as to what is appropriate in their relationships with their patients. For patients and physicians to continue a comfortable, trusting relationship, this dilemma needs attention.

The Alabama Board of Medical Examiners (BME) and the Medical Association of the State of Alabama (MASA) have made a concerted effort to educate physicians in Alabama on physician/patient boundary issues and prevention of allegations of professional sexual misconduct. This educational effort has not stopped with the physician's practice but has included any non-physician involved in the investigative and decision making process with the state medical board.

Nationally recognized authorities participated during a symposium on professional sexual misconduct developed for the BME and Medical Licensure Commission in August of 1994. Material in this symposium included, 1) the incidence and types of professional sexual misconduct as reported nationally, 2) what physician actions constitute boundary violations, 3) characterization of the physician who may be involved with complaints of sexual misconduct, and 4) profile of the patient who may be vulnerable to sexual involvement with the physician. Consistent with the concept that professional sexual misconduct is "the regulatory issue of the nineties,"[3] the Alabama board is making every effort to remain current.

MASA's Continuing Education Department, together with the BME, presented a continuing educational program which was made available to all Alabama physicians on December 3, 1994 in Birmingham, Alabama, titled "Sexual Problems in Medical Practice." The seminar was attended by 78 Alabama physicians. The program provided 6.5 hours in Category 1 of the Physicians Recognition Award of the American Medical Association. This seminar's objectives included background on sexual abuse problems and the kinds of sexual problems encountered, use of chaperons, understanding the potential of sexual harassment claims, identifying common errors in maintaining clear boundaries with patients, and the applicable laws, policies and procedures in Alabama relating to sexual misconduct.

The Physicians Recovery Network (PRN), in conjunction with the Communications Department of MASA, developed a special issue of Alabama Medicine in December of 1994 devoted exclusively to issues surrounding sexual misconduct in the physician/patient relationship, entitled "The Physician and Sexual Boundary Issues."[4] This issue included contributions from authors published in national medical literature. The journal contained all aspects of the relationship between a physician and patient that might be suggestive of or have the potential to be considered a boundary violation. Reprints from this issue of Alabama Medicine have been requested by many physicians both within and outside the state of Alabama.

Expanding on the December 1994 issue of Alabama Medicine and the BME symposium in August of 1994, PRN has developed ongoing programs to educate hospital physician groups, county medical societies, and other physician groups on sexual boundary issues in the practice of medicine. Through July 1995 PRN has presented this program to 26 groups throughout Alabama which have been attended by over 300 physicians collectively.

Beginning with the fall 1993 issue of the Alabama BME Newsletter,[5] both the BME and MASA have endeavored to keep Alabama physicians current on this "issue of the nineties" and to ensure that patient safety and trust in the physician/patient relationship is maintained. The ongoing effort to reach every licensed physician stands out as a model for other states.

1. Gabbard, G.O., Nadelson, C.; Professional Boundaries in the Physician-Patient Relationship, JAMA, 1995; 273: 1445-1449.
2. Sexual Abuse in the Doctor/Patient Relationship, Statement for the Profession and the Medical Council of New Zealand, P.O. Box 11-649, Wellington, New Zealand.
3. Gregory, G.R., J.D., cited by Reaves, R.P., J.D.; Sexual Intimacies with Patients: The Regulatory Issue of the Nineties, Federation Bulletin, 80(2), 1993; 83-90.
4. Summer, G.L et al; The Physician and Sexual Boundary Issues, Alabama Medicine, 1994; 64(6): 4-19.
5. Summer, G.L., Lightfoot, W.M.; The Implication of Sexual Misconduct in a Physician's Practice, Alahama Board of Medical Examiners Newsletter, Fall 1993.

The Discovery of Insulin

*Gayle M. Herrington, M.D.**

INTRODUCTION

The discovery of insulin is one of medicine's greatest miracles. Prior to the discovery of insulin, most adult diabetics (except those with very mild diabetes) lived only five or six years after diagnosis, and that was only if they followed the very strict undernutrition diet that was used at that time. Child diabetics usually lived only a year or two after diagnosis.[1] The story of the discovery is one of the more riveting tales of modern (20th century) medicine.

THE PEOPLE:

Frederick Banting

Frederick Banting was born on November 14, 1891 in Ontario, Canada. His family had intended for him to go into the ministry. In school, he was regarded as a good athlete and a mediocre scholar. In 1910, he initially enrolled in college at Victoria College, a Methodist college in Toronto, with the intention of entering the ministry, but in 1912, switched to medicine, and enrolled in the University of Toronto Medical School. He enlisted in the Royal Canadian Army in 1915 and served m the Medical Corps. He was promoted to Captain following graduation with the M.C. degree in 1917, and was sent to France where he was wounded in the right arm. He received the Military Cross for valorous conduct and was discharged in 1919. He returned to Canada as a trainee in surgery where he focused on orthopedics. He completed, his training in 1920, and hung out his shingle on July 1, 1920. Money was tight, and his practice was growing too slowly to support him financially. To supplement his income, he took a job as a demonstrator in anatomy and surgery at Western University Medical School.[2]

J.J.R. Macleod (John James Richard Macleod)

J.J.R. Macleod, the son of a minister, was born on 1876 in Cluny, Scotland. He studied medicine at Marischal College, University of Aberdeen, graduating with honors in 1898. He continued his studies at Leipzig and Cambridge, and also held brief appointments at The London Hospital Medical College. In 1903, he left The United Kingdom for a position as a Professor of Physiology at Western Reserve University in Cleveland, Ohio, where he would spend the next fifteen years establishing his reputation as one of the foremost experts in the field of carbohydrate metabolism. He was a professor well-versed in his discipline, a prolific researcher, and was an was also an accomplished scientific writer at both the introductory and advanced levels. His early work had been with Leonard Hill on intracranial circulation, but he became interested in metabolism and the body's use of carbohydrates. Between 1903 and 1913, he published a long series of papers entitled "Studies in Experimental Glycosuria", and in 1913 he wrote a monograph, *Diabetes: Its Pathological Physiology*, which summarized the work. But in 1914, he reached an impasse in his work in the cause of hyperglycemia as the experimental techniques at that time were too limited. In 1918, he returned to the University of Toronto to accept the chair of physiology, where he focused his research to explore the centers of respiration.[4]

Charles Herbert Best

Charles Best, who was the son of a small-town general practitioner, grew up on the coast of Maine. He graduated second in his class from the Honor Physiology and Biochemistry course at the University of Toronto in 1921, and was employed by J.J.R. Macleod as a student assistant and demonstrator in physiology. Professor Macleod had selected Best as one of his most promising students, and often invited him to his home. Best was planning on working on his Master of Arts degree under Macleod, and thought he might eventually become a surgeon. He may have had some special interest in diabetes research since one of his aunts died from the disease in 1917. He developed more precise methods for measuring glucose concentrations in blood or urine.[4]

J. B. Collip

J. B. Collip, the son of a florist, was born in Belville, Ontario. In 1916, he received his Phd. in biochemistry from the University of Toronto, and became a professor at the University of Alberta. In 1920, he was promoted to full professor in charge of the department of biochemistry. He was interested

•Presented to the Tinsley R. Harrison Medical Student Society, UAB, on 13 December 1994. Reprints can be obtained from James A. Pittman, Jr., M.D., SDB-75, UAB Medical Center, Birmingham, AL 35294-0007.

in the study of glandular secretions and the making of tissue extracts, and had written a summary article on internal secretions. In 1920, he studied the impact of injections of various tissue extracts and of adrenalin on blood pressure in animals. His deepest commitment was as a research scientist, and he spent long hours in the lab observing the physiological effects of various ingredients. He also, by 1921, he had over twenty academic publications.[4]

EARLY HISTORY OF DIABETES AND DIABETIC THERAPIES

The word "diabetes" originates from the Greek word meaning siphon or pipe-like. Diabetes had been recognized thousands of years ago by the Egyptians and Greeks by its classic symptoms of frequent urination (polyuria), constant thirst (polydipsia), and excessive hunger (polyphagia). Early physicians found the urine of diabetics was sweet to the taste, and the Latin word for honey/sweet, "mellitus", was added to distinguish it from diabetes insipidous in which large volumes of non-sweet urine is passed. The problem in diabetes is an inability to burn much of the simple glucose made from food, since the glucose remains in the blood instead of being absorbed into the cells. One of the roles of insulin is to enable transport of glucose and other substances into the cell.[4]

Prior to the discovery of insulin, the life expectancy of **juvenile** diabetes (insulin dependent diabetes mellitus) was less than one year from the time of diagnosis. The diabetes would cause the body to waste away as its tissues were broken in the body's effort to obtain a supply of energy. Once a diabetic went into ketoacidosis, death was only a few days away. The patient would usually be Unable to take food or drink, would develop a restless drowsiness, and gradually slip into unconsciousness and into a deep diabetic coma. As the victim went into coma, they would take huge gasps (Kussmaul respirations) of air in an effort to correct the metabolic acidosis by expelling CO_2. Once they slipped into a coma, death occurred within hours. [4]

Older or adult onset diabetics had a longer life span than did juvenile diabetics. The cause of death was usually from infections and the complications of diabetes. Over a period of time, there was damage to the small vessels of the body in the eyes, kidneys, and the extremities resulting in the development of cataracts, blindness, severe foot and leg infections that were often accompanied by gangrene.[4]

There were a number of early therapies attempted. Most of these, which included bleeding, blistering, and doping did more harm than good. During the late 1850s, a French physician, Piorry, advocated the intake of' large quantities of sugar to compensate for the large losses flowing out in the urine. The first important breakthrough occurred when doctors realized that the extra food exacerbated things and began to prescribe a decreased carbohydrate intake. Bouchardat, a French physician, noticed the disappearance of glycosuria in some patients during rationing while Paris was under the German occupation in 1870. He began developing individualized low-calorie diets with the idea that if the system cannot handle the food it is given, then the food intake should be decreased in order to reduce the strain on the system. He observed that exercise increased a diabetic's tolerance of carbohydrates. Then, as is now, the single most difficult problems that physicians face in treat diabetes is diabetics' unwillingness to follow diets. In 1902, von Noorden. a German, announced his oat cure which allowed a diabetic to increase their carbohydrate intake as long as it was some form of oatmeal. This was the most popular of a series of carbohydrate "cures."[4]

PROGRESS BEFORE BANTING AND BEST

In 1869, while a German medical student, Paul Langerhans described a second system of cells scattered among the acini, but was unconnected to them. The acini were known to secrete the normal pancreatic juice, but the function of the second heretofore unrecognized cells was unknown. Several years later, a French scientist, Laguese. who was an expert about the pancreas, named these cells the islets of Langerhans and suggested they performed an additional function in the body, other than the secretion of digestive juice.[4]

A major breakthrough connecting the pancreas and diabetes occurred in 1869 at the medical clinic of the University of Strasbourg. Osker Minkowski and Joseph von Merring demonstrated in dogs that the absence of the pancreas causes diabetes. This was the discovery that the pancreas regulated sugar metabolism. In 1893, Hedon, a French researcher proved that in dogs, complete pancreatectomy causes diabetes. He developed the Hedon technique, which was a two-stage procedure. In the first stage, he removed all but a small pedicle of healthy pancreas. This was still attached to its blood supply, and was grafted under the dog's skin. The dog did not become diabetic. Final removal of the pedicle immediately resulted in diabetes. This experiment proved that total absence of the pancreas results in diabetes, and that the pancreas did indeed have two functions. The digestive juices were the *external* secretion, and its other function was to produce an *internal* secretion that was secreted directly into the bloodstream and regulated carbohydrate metabolism. Eugene Opie, an American, in 1901 at John Hopkins University in Baltimore, showed a pathological connection between diabetes and dam-

age to the islets of Langerhans. From this point on, it was believed that the islets of Langerhans produced an internal secretion of the pancreas that was key to the control of carbohydrate metabolism. In 1902, Bayliss and Starling discovered secretin (secreted from duodenal epithelium and triggers the flow of pancreatic enzymes).[4]

The term "hormone" is commonly thought to have originated from the British physiologists, Bayliss and Starling. But, as explained by Bayliss in an early edition of his book on physiology, the term was originally suggested by W.T. Vesey to Sir William B. Hardy of Gonville and Caius College, Cambridge, to describe chemical messengers secreted from ductless glands directly into the bloodstream ("internal secretion") and carried to other tissues of the body, where they stimulated reactions that affected the the whole body. This was in contrast to substances which are secreted through duets and into body cavities. The word "hormone" is derived from a Greek verb, hormao, meaning to put into quick motion, to excite or arouse. Professor E.H. Starling first used the term publically during his Croonian Lectures at the Royal College of Physicians in June 1905 in his lecture on "On the Chemical Correlation of the Functions of the Body."[5]

Once it was known that the pancreas controls diabetes, there were many initial efforts to treat the disease with pancreatic extracts. Minkowski tried extracts of whole pancreas without separation of the internal and external secretions. Early results were mixed, tending mostly towards the negative as some extracts had no effects, and other had toxic effects resulting in death. Laguese speculated that part of the problem was due to destruction of the internal secretion by the external secretion. He suggested using extracts made from fetal pancreas as acini cells develop much later than do Langerhan cells. Georg Ludwig Zuelzer, a young internist in Berlin, tried his extract in animals with success so was encouraged to go further. On June 21, 1906, he tried his extract on a human comatose diabetic with dramatic results. There was reversal of the coma and an improvement in appetite. The patient continued to do well until the extract was gone, and then the patient went back into a diabetic coma on June 30 and died on July 2. He called his extract "acomatol." He had numerous practical difficulties in carrying out his experiments as materials were difficult to come by and the extract was technically difficult to make. Schering Drug Company agreed to provide him financial and technical help. But unfortunately, after his first couple of successes the rest of his patients developed severe toxic reactions to the injections, consisting of vomiting, high fever, and sometimes convulsions. He published results in 1908 touting the extract as a viable treatment. J. Forschbach, a worker in Minkowski's clinic, tested samples on three dogs and three humans. There was reversal of glycosuria, followed by the onset of severely toxic reactions. After noting that some impotent extract caused no ill effects, he concluded that the cause of the potency and of the toxic side effects were the same, the toxic effects outweighed the benefits, hence there was no future in the extract. This resulted in Schering withdrawing its support from Zuelzer. In 1911, Zuelzer convinced the Hoffman-La-Roche chemical firm to fund a small lab and provide some coworkers for him. Zuelzer took out an American patent on his extract. The animals that received a dose of extract from his first big batch all went into severe convulsions. He concluded it was toxic side effects. He was prepared to try another round of experiments in 1914, but he was called to the front when the war began. Unfortunately, the major impact of his work was to set back the search for an effective pancreatic extract. The combination of his published findings and Forschbach's reports convinced researchers of the impossibility of producing a safe and effective extract.[4]

E.I. Scott, a student of the University of Chicago in 1911-12, was deeply affected by the death of a friend from diabetes so he decided to continue the search for the internal secretion of the pancreas as his thesis for his masters degree. Scott reasoned that previous failures had been caused by the proteolytic digestion of the internal secretion by the external secretion. He figured the answer lay in isolation of the internal secretion, which he tried to accomplish by inducing atrophy of the tissues producing the external secretion through pancreatic duct ligation. But, he found it almost impossible to get the pancreas to atrophy after pancreatic duct ligation. Next, he went to alcohol extraction of the internal secretion, which gave initial success when tried on animals. In his thesis, he concluded that the internal secretion from the pancreas controlled sugar metabolism, and that with that use of proper methods the internal secretion from the pancreas controlled sugar metabolism, and that with the use of proper methods the internal secretion could be extracted and still retain its activity. But his thesis advisor, Anton Carlson, noticed that the injections were followed by a slight increase in body temperature, which by itself, could be responsible for the decrease in blood sugar. It was also possible that the extract may act by a depressor or toxic effect on the pancreas. Before giving up his work, Scott discussed his results with some of the other experts in the field, which included J.J.R. Macleod, who was working on his own search for the internal secretion. He discouraged Scott from pursuing it further.[4]

In 1913, Dr. Frederick Allen concluded that pan-

creatic preparations were both useless and harmful. He noted that diabetes was a problem of carbohydrate, fat, and protein metabolism, hence all food tended to overburden the system. He developed a restricted calories diet, which involved the concept of dietary control of symptoms. His treatment was known as the "starvation treatment" of diabetes, and was strongly supported by Dr. Elliott P. Joslin, the most prominent specialist in diabetes. This was the best available treatment at the time.[4]

In 1915, Israel Kleiner, an American, began experiments with pancreatic extracts and studying blood sugar. He published results in 1919 that provided the most convincing evidence as there was a consistent drop in blood sugar. But, he was plagued by the slight toxic symptoms of a mild fever associated with the extract. For an unknown reason, he never did any further work on the problem.[4]

Nicolas Paulesco was professor of physiology in the Romanian School of Medicine in Bucharest, and while a medical student became interested in the work of von Mering and Minowski on the idea of an antidiabetic hormone in the pancrease. In 1916, he relieved symptoms briefly in a diabetic dog with injections of pancreatic extract. But, his work was interrupted when Romania became involved in the war, and Bucharest was occupied. Four years later, he was able to resume his work and again obtained the same results which were published in French in 1920.[6] He also proved that fever induced in dogs did not cause a decrease in blood sugar. His experiments were more varied than any of the others had been.[4]

THE WORK OF BANTING AND BEST

On Sunday, October 30, 1920, Frederick Grant Banting was preparing a lecture about the pancreas to give to one of his classes the following morning. He intended to read himself to sleep with the latest issue of *Surgery, Gynecology, and Obstetrics*, but his attention was caught by an article titled "The Relation of the Islets of Langerhans to Diabetes With Special Reference to the Cases of Pancreatic Lithiasis," which described the effects of a stone obstructing the pancreatic duct leading to destruction of the exocrine pancreas duct may enable isolation of the internal secretion. He decided to pursue this and presented his idea to J.J.R. Macleod who agreed to provide the lab, ten dogs, and assistant for eight weeks, and facilities for performing blood and urine tests. Charles Best was assigned to work with Banting. Contrary to what is commonly believed, Macleod was around for the first month of work prior to leaving town for his summer holiday.[4]

Work began on Tuesday, May 17, 1921, and it went badly at first. By the end of the first week, seven out of ten dogs were dead. Banting and Best bought dogs on the streets of Toronto. Occasional double numbering is noted in the records, i.e., later, a dog with the same number as one that had just died appears in Banting's notebook. They utilized the two-step method of pancreatectomy developed by Hedon. Within the first seven weeks, 14 of the 19 dogs had died following surgery, and there was no sign of pancreatic atrophy in the five living dogs. By this time, most of the budget that had been supplied by Macleod was gone, so Banting sold his Ford automobile to buy more dogs. Finally, on Saturday, July 30, 1921, an atrophic pancreas was identified in one of the five surviving dogs from the first phase of the project.[4]

Macleod had wanted Banting and Best to graft pieces of degenerated pancreas into diabetic dogs as an initial approach, followed by the injection of an emulsion of degenerated pancreas into diabetic dogs as a follow-up approach. But Banting decided to make an extract of the atrophied pancreas. On Saturday, July 30, 1921, an extract of atrophied pancreas injected intravenously, successfully lowered the blood and urine sugar of a diabetic dog. The dog died the next day, but no autopsy was done. Prior to death, the blood sugar had begun to increase, but it never reached the levels usually seen in depancreatized animals. The parameters that were used to measure and follow the progress of the research included blood and urine glucose and the dextrose to nitrogen ratios which were thought to be an accurate reflection of the diabetic state (3.65-1=diabetic state).[4]

The dextrose-nitrogen ratio is the ratio of dextrose to nitrogen in the urine. Each 6.25 grams of protein, whether from food or its own tissues, metabolized by an animal yields 1.0 gram of urinary nitrogen, and 58% of this 6.25 grams of protein is metabolized to glucose, hence 6.25 x 0.58 yields 3.65 grams of glucose. In a nondiabetic animal, this glucose would be oxidized and would not appear in the urine. But in the diabetic animal that was unable to metabolize this glucose, all or part of it would appear in the urine along with the normal urinary nitrogen, thus the D:N ratio. The ratio of 3.65-1 would be indicative of severe diabetes, as this is the highest ratio which is possible to obtain.[7]

On Monday, August 1, a second dog in a coma on the brink of death was successfully treated with the extract. The blood sugar decreased from 0.50 to 0.42 percent (normal range=0.85-0.150 percent or g/L) resulting in a reversal of coma. Additional extract decreased the blood sugar to 0.30%, but the dog lapsed back into a coma and died. Again, no autopsy was done. By mid August, it was evident that the extract could keep a depancreatized dog alive and in apparent good health. Initially, they called the extract **"isletin."**[4]

Additional varied experiments followed in which they demonstrated some findings and came to some conclusions. They proved that extracts of other organs (liver and spleen) had no effect on the blood sugar. They demonstrated that boiling inactivated the extract. Unknowingly, they induced hypoglycemia prior to the death of the dog, and Banting and Best thought the injection had caused anaphylactic shock or thrombosis. But, autopsy revealed widespread infection resulting from the surgery, which was considered the cause of death. This concluded the first series of experiments.[4]

The second phase of the work began with trials of extracts of fresh whole pancreas, which lowered blood sugar from 0.30 initially, down to 0.19 thirty minutes later. Within one hour it had decreased to 0.17, and within one and one-half hours, it rose to 0.20. The fresh gland extract had a more potent effect in lowering blood sugar, but they reported that fresh extract was much weaker than the from atrophied gland. They had failed to notice that it was actually stronger, a **major** error.[4]

Banting and Best performed a number of other experiments. They used secretin in an attempt to exhaust the pancreatic supply of external secretion as an alternative method of avoiding the external secretion. It was extremely successful. Failed efforts to "burn" sugar in the test tube with the use of extract was erroneously recorded as successful. Subcutaneous injections were tried for the first time, and resulted in blood sugars which remained stable and did not rise. Dilution was ruled out as the cause of the decrease in blood sugar in the following experiment. To control for diurnal variation, injections were made at the same time every day. By measuring blood sugar after an injection of 100 cc. of saline, they were able to show that the decrease in blood sugar was not due to dilution from a large volume, as there was no decrease of blood sugar levels following the injection. By measuring the hemoglobin level before and after injection of the extract, they demonstrated that there was no appreciable thinning of the blood.[4]

Paulesco's work was misinterpreted by Banting and Best, and they conclude that he did not get good results from injections into peripheral veins when in fact he did. But, unfortunately, Banting could neither read nor speak French, and Best had very little knowledge of French, hence a language barrier probably accounted for the misinterpretation of Paulesco's paper.[6] Paulesco also proved that his extract lowered the blood sugar in both normal and diabetic animals. Banting and Best found that fetal pancreas was a good source of the extract as the acini cells are not numerous, and the external secretion may not yet be potent since it would not be needed until after birth.[4]

On November 10, 1921, Banting and Best completed their first paper, and it was published February 1922 in the prestigious *Journal of Laboratory and Clinical Medicine*. This paper contained minor factual errors, including the misreading and misinterpretation of Paulesco's work. They stated that they could not yet justify human clinical use as they did not yet have a therapeutic agent. The production of large batches of the extract became possible when they discovered that ethanol extraction of the internal secretion from fresh pancreas eliminated the need for fetal or degenerated pancreas.[4]

J.B. Collip joined the project at Banting's request in December 1921 as the pace was speeding up. Collip made a number of important findings. He showed that the extract was effective across species as it lowered blood sugar in normal rabbits. That the extract lowered the blood sugar in <u>normal</u> rabbits, gave a quick and easy way to measure the potency of a batch of extract. Its strength could be measured by its effect on the blood sugar of a normal rabbit. He demonstrated that the extract could abolish ketosis, and enable a diabetic animal's liver to form glycogen. Collip also refined the extraction and purification process.[4]

Banting presented his paper at the December 30, 1921 session of the American Physiological Society at Yale University in New Haven. He did not present well and failed to convince all of the audience that his results proved the presence of an internal secretion of the pancreas, the primary object of the work, any better than had previous investigators. Since he had not kept temperature records (except for <u>one</u> reading showing fever), Banting was unable to address questions about toxic effects such as fever. Macleod came to Banting's defense using the word "we," which Banting construed as evidence of Macleod trying to take credit for his work – i.e., to steal his results.[4]

Macleod turned his whole lab over to research on the insulin extract and a rough division of labor was worked out as follows; Clark Noble was added to the group to work on rabbit testing and the glycogen experiments. Charles Best and Dr. John Hepburn were to do respiratory quotient tests – considered to be a good measure of carbohydrate metabolism. Collip was to try to purify the extract sufficient for use in clinical trials. Banting did whatever surgery the group required, and may have been expected to play an important role in the impending clinical trials because he was more-or-less the only practicing physician. Collip figured out that the toxic reactions with convulsions is hypoglycemic shock.[4]

On January 11, 1922, the first human clinical trial is performed on a fourteen year old boy. Leonard Thompson was admitted to the Toronto General Hospital in ketoacidosis, and had almost

reached the end of the life expectancy of a diabetic child. He was pale and emaciated, weighed only 65 pounds, had flabby muscles, had dry hair which was falling out, and he had the odor of acetone on his breath. Usually, someone at this stage was expected to have gone into a coma and died within a few weeks.[1] He was treated with insulin extracted from fresh beef pancreas, and showed dramatic improvement. The insulin was then stopped for 10 days, so that they could be sure that his improvement was due to the insulin and not from some unknown factor. His clinical condition deteriorated, and he had concomitant increase in his blood and urine glucose, and acetone. Ten days later, the insulin was resumed. The blood and urine sugar decreased, and the boy began to gain weight. This was the first unambiguously successful clinical trial of the internal secretion, and was the first time in medical history that a diabetic child had been restored to health. This was only a little over a year after Banting had had his idea and was only eight months after Banting and Best had begun their experiments.[2]

On April 1922, the Toronto group prepared a summary paper describing all of the work which had been done so far,

1. Bantings's idea about isolation of the internal secretion
2. The early experiments of Banting and Best
3. Collip's purification
4. The clinical trials and results
5. The hypoglycemic effects
6. The respiratory quotient
7. Liver/glycogen findings
8. Ketonuria findings
9. Name given to the extract, "INSULIN"

The paper was presented by Macleod on May 3, 1922 at the meeting of the Association of American Physicians. Many researchers were convinced that the Toronto group had isolated the internal secretion fairly free of toxic material – an **epoch making discovery.**[4]

Dr. Joe Gilchrist of Toronto was a close friend and medical school classmate of Banting's and was one of the first patients to receive insulin. He voluntarily submitted himself for experimental purposes. He had developed his diabetes in late adolescence and had managed to maintain fair control through a rigid diet. But, after an attack of the flu in the autumn of 1921, he was no longer able to control his blood sugar through diet alone. He began losing weight rapidly, his strength decreased, and he developed symptoms of hunger and thirst. It was through Dr. Gilchrsit's body that Banting and his team were able to learn at what times, in relation to meals and sleep, it was best to administer insulin. He was also the first human to undergo and then report on the experience of receiving an overdose of insulin.[1]

All of the early patients had to be guinea pigs because neither Banting nor any of the other clinicians knew precisely how much insulin was needed to maintain the proper blood sugar level of various type of patients.[1]

The Nobel Prize in Medicine and Physiology was awarded to Banting and Macleod in 1923. Banting promptly shared his with Best, and Macleod shared his with J.B. Collip. The omission of Best and the inclusion of Macleod as a co-recipient resulted in controversy that continues to this day.

THE CONTROVERSY

CONTRIBUTORS TO THE DISCOVERY OF INSULIN:

Frederick Banting

Had the idea for the extraction of insulin. He lacked knowledge of the field of endocrinology, was inexperienced at research, unsure of his methods, and ignorant of the testing procedures he would have to use.

J.J.R. Macleod

Provided the money, the lab, the dogs, and advice for the plan of the research, and taught Banting techniques of pancreatectomy. Also taught Banting how to prepare an extract. After their initial success in lowering blood sugar in dogs, Macleod gave instructions for controls, suggested problems with their findings and outlined other experiments to make the results more convincing.

Charles Best

A biochemist who provided technology for measuring urine and blood sugar which was crucial for success.

J.B. Collip

A biochemist who developed techniques for isolating and punfying the insulin so that it was suitable for human trials. He also discovered before 12/1921 that the extract cleared up ketoacidosis. He also figured out that it caused hypoglycemia.

DISCUSSION

The controversy actually began in December 1922 with a scathing critique in a letter written by Dr. Ffrangron Roberts, a physiology researcher in Cambridge, England, to the British Medical Journal. The critique was immediately rebuked by Dr. Henry H. Dale as a belittlement of a great achievement, a view that prevailed in medical and historical circles for the next three decades. The oral history about he discovery of insulin tended to be more interesting

than the written history well into the 1950s. A critical silence was maintained until 1954, when Joseph H. Pratt published a major critical review of the work, noting the contributions made by Macleod and Collip in refining both Banting's and Best's flawed experiments, and their crude pancreatic extract. He concluded that credit for the discovery of insulin preparation which could be used in treatment of diabetes belonged to **all four men**. This prompted, a sharp reply from a medical historian, Dr. W.R. Feasby, in 1958 that the records of Banting's and Best's work prove that Banting and Best, together, discovered insulin with the others helping in its development.[4]

Ian Murray, a Scots historian during the late 1960s and early 1970s, believed that Nicolas Paulesco, a Romanian, had actually discovered insulin, and that Banting and Best merely confirmed Paulesco's findings. This revived Romanian interest in Paulesco, and resulted in members of the Romanian School of Medicine in Buchrest mounting a campaign to have Paulesco given his due. The campaign resulted in the International Diabetes Foundation reviewing the history and concluding that while Paulesco's extract and Zuelzer's extract may have contained insulin, it was the Canadians who made it suitable for the treatment of diabetes. The Rumanians were not satisfied and suggested that:

1. Banting may have deliberately distorted the work done by Paulesco.
2. Macleod probably blackmailed Banting about falsifying the information about paulesco's work unless he shared the credit and glory.[4]

This raises some questions:

1. Why did Macleod receive one-half of the Nobel prize?
2. Why is insulin discovered in a place that has no particular stature in the world of medical research? And by two inexperienced researchers?

According to Dr. John R. Henderson, Reader in Physiology at St. George's Hospital Medical School in London, and author of an account of the discovery of insulin, **nobody** actually discovered insulin. Rather, that it existed first as an idea (Laguesse), then a proven hypothesis (Gley, Zuelzer, Allen,) and then as a practical way of treating diabetes (Paulesco and Banting). He quoted J.S. Mill as having said that a man with a conviction is worth twelve men with ideas. Banting and Paulesco are considered the only men with a conviction; the rest were all just idea men. It is the conviction that finally leads to the real results.[6]

In 1948, fifteen years after the death of J.J.R. Macleod, his personal account of the events leading to the discovery of insulin was discovered. During the mid 1950s, the president of the University of Toronto prevented the publication of Macleod's personal account. In 1978, Lloyd Stevenson finally published the Macleod document in the Bulletin of The History of Medicine.

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Diabetes, Insulin, And Alabama

by Buris R. Boshell, M.D., F.A.C.P.[1]

First, I think we should thank Gayle Herrington for the excellent presentation. The discovery of insulin is one of the most dramatic major landmarks not only in endocrinology but in all of medicine and medical history. And it has ties to Alabama going back almost to the very beginnings Mrs. Herrington just described.

I became very much interested in diabetes as I was a fourth year medical student at Harvard by taking an elective with Elliott P. Joslin, M.D., founder of the Joslin Clinic at the New England Deaconess Hospital, a few blocks from the Peter Bent Brigham Hospital and Harvard Medical School. The Joslin Clinic was devoted to the care of patients with diabetes mellitus and at that time was widely considered the best place in the world to obtain such care.

At that point in time there were two schools of thought about diabetes, the Joslin school and the Tolstoy school. Joslin in Boston believed in tight control; and Tolstoy in New York merely believed in keeping people out of acidosis. Joslin, however, believed that you should keep them so closely regulated that they would have insulin reactions from time to time; i.e., hypoglycemia.

I moved back to Alabama in 1959 into the new Division of Endocrinology and Metabolism just established by S. R. Hill, Jr., M.D., in Walter B. Frommeyer's Department of Medicine. I began to learn some very interesting things about diabetes. First of all, Dr. Michael Smogyi of St. Louis began to spend the winter months with me in my laboratory, and it turns out that in addition to discovering a number of the enzymes for blood sugar determinations and so forth, he came very close to being the first man to discover insulin.

I also came under the tutelage of Dr. Emmett Carmichael, who was Chairman of Biochemistry then, and he told me some very interesting stories about Seale Harris, whom I knew fairly well, since he often visited Dr. Groce Harrison, father of Tinsley Harrison, and I lived with and cared for Dr. Groce Harrison while I was a medical student. Seale Harris was quite interested in diabetes and sugar metabolism back in the 1920s when Banting and Best discovered insulin. As a matter of fact, Seale Harris visited Toronto on several occasions. While there, he noted some of the patients who received too much insulin went into hypoglycemia, and he made the statement that he had seen patients at home in his practice who without any insulin had the same symptoms. He came back and documented hypoglycemia and was given credit for the discovery of spontaneous hypoglycemia. I believe he published this in *The Journal of the American Medical Association* about 1924,[1] insulin having been discovered in 1921.[2,3]

Somogyi pointed out that Joslin was wrong in the extremely tight control of his diabetics and that the hypoglycemia that resulted caused both insulin resistance and brittle diabetes. So we quickly melded both the Joslin and Somogyi philosophies together and this formed the basis for our treatment, which has now been justified by the recent findings of the studies sponsored by NIH, which indicate very clearly that control does help prevent complications.[4]

When I first came to the medical school at UAB in 1949, there were two major factions as far as internal medicine was concerned, McLester and Seale Harris. Both of them were interested in metabolism, and actually Dr. McLester brought Tom Spies, M.D., who was noted for his outstanding work in pellagra and other vitamin deficiencies.

Subsequently I had the opportunity to treat the first diabetic in Alabama to receive insulin, Frances Smyer (Mrs. Sidney William Smyer, Sr.). Fortunately, Mrs. Smyer was a very bright lady who was compulsive and adhered to a very careful dietary and insulin program, and she actually lived to a ripe old age. When she first started in 1922, of course, the only insulin that was available was regular insulin, which meant she had to take four shots a day. As the other long-acting insulins were developed, for example first of all protamine zinc insulin or PZI, people became a little more careless about their diabetes. When one looks back, there were fewer complications during the era of 1922 through 1936, when regular crystalline insulin was the only insulin available. This again has been corroborated by the recent study from the NIH. Diabetes to me has always been a very intriguing disease. It is of interest that in

1 Based on the discussion of the paper on "The Discovery of Insulin," by Gayle M. Herrington, M.D., presented to the Tinsley R. Harrison Medical Student Society of UAB on 13 December 1994. Dr. Herrington was then a fourth year medical student.

spite of the fact that there have been five or six Nobel Prizes awarded in various aspects of diabetes, none of these has actually been awarded to a true endocrinologist. They have come from the work of the basic scientists and associated people. Dr. Banting was a surgeon; Dr. Macleod was a physiologist; and Dr. Best, who did not actually receive the prize but shared Banting's, was a medical student. In 1947 Dr. Bernardo A. Houssay, a brilliant Argentine physiologist, won a Nobel Prize for his work relating diabetes mellitus to the pituitary gland. I later had the opportunity to meet Dr. Houssay, and it is of interest that he submitted the article to several American journals, and it was turned down for publication on several occasions. He received a refusal notice stating that his findings did not agree with the common way of thinking. Fortunately, Dr. Houssay was not a common thinker, and people finally realized the importance of the work, and he received a Nobel Prize.

Dr. Frederick Sanger in Britain received the Nobel Prize in Chemistry (1958) for work related to diabetes, because they worked out the amino acid sequence of insulin. Earle W. Sutherland, Jr., M.D., discovered the "second messenger" cyclic AMP, which is important in hormone action, while he was Chairman of Medicine at Case-Western Reserve medical school in Ohio in 1956. He moved to Vanderbilt as Professor of Physiology in 1963, and in 1971 he received the Nobel Prize for this work. In 1977 Dr. Rosalyn S. Yalow in New York received a Nobel Prize in Physiology or Medicine for her work with S. A. Berson, M.D., in 1955-56 which led to the development of radioimmunoassay. That work in the 19508 was on the pathogenesis of diabetes mellitus. She was not an M.D., but a Ph.D.

Thus, diabetes has a very common touch with Alabama in several respects. Seale Harris received the acknowledgement as being the discoverer of hypoglycemia due to "hyperinsulinism." Somogyi, who worked here several winters, made major contributions to the field of diabetes. Houssay was an acquaintance of mine and helped educate me about the importance of doing your own thinking. Yalow made several visits to Birmingham to give talks in my diabetes program. And, although Dr. McLester did not do a lot of basic work, he was a prominent Birmingham physician and President of the American Medical Association, and he called attention to the clinical aspects of diabetes.[5]

Thus, the outstanding treatise by Gayle Herrington came at a good location with a long tradition in the care of patients with diabetes.

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Dr. Boshell, a native of Bear Creek, Alabama, attended the School of Veterinary Medicine at Auburn, graduated from the University of Alabama, Tuscaloosa, and from Harvard Medical School. He took his house staff training under the famous endocrinologist George W. Thorn at the Peter Bent Brigham Hospital, where he finished by becoming Chief Medical Resident for an unprecedented 2 years (two "terms" as Chief Resident). He also studied during a fellowship under Elliott P. Joslin, M.D., at the nearby Joslin Clinic before returning to Alabama and the medical school in Birmingham, where he eventually became the Ruth Lawson Hanson Professor of Endocrinology and Metabolism and was instrumental in construction of what was then "the Diabetes Hopsital," now the B.R. Boshell Building of the Department of Medicine, UAB. He currently practices at Medical Center East, where he heads the program in Diabetes and Endocrinology.

Groin Hernia: A Current Perspective

*by Henry L. Laws, M.D.**

Groin hernias constitute one of the most common afflictions of humans at all ages, especially males. Even after intense scrutiny, study, and surgical attack for hundreds of years the best approach affording uniform correction remains under debate, and perhaps, unattainable. Topics receiving most attention at this time include the type anesthesia, the better approach (open or endoscopic), use of mesh or no mesh, specific technique, acceptable lost time from work. In the Middle Ages traveling hernia specialists went from town to town espousing expertise. Only persons with desperate conditions would submit to the operation. The most important equipment for the operation were four strong young men to hold the patient down. Results were predictably dismal; hence, the surgeons moved on immediately. The modern era was begun with the uniform use of anesthesia and antisepsis and began about 1890. Though a number of techniques have been described in the last hundred years, the work of Eduardo Bassini set the standard for the various modern repairs.

In the past thirty years there has been a progressive shift to the use of mesh repairs, toward local anesthesia, and toward early return to work. Within the past five years, there have been many advocates adopting and recommending endoscopic or video type repairs. The non surgeon practitioner understandably may be confused about the current status of surgery for groin hernias.

Indications for Operation

Infants probably deserve repair as soon as convenient after a hernia is discovered. (Table 1) Experienced pediatric surgeons will explore the groin for an inguinal hernia if they get a reliable history from the mother of swelling in the appropriate area even though the surgeon cannot demonstrate the hernia at the time of the examination. Most pediatric surgeons explore the contralateral groin in infants up to age two. There is still debate at what age level it is considered unnecessary to explore the contralateral groin. Surgeons at the Children's Hospital in Birmingham actually visualize the contralateral groin from within utilizing a 1.9 mm Storz endoscope which can be inserted through a #12 angiocath.[1]

Table 1

Hernias Deserving Repair

Type	
Pediatric Age Group	All
Femoral Hernias	All
Indirect Hernias	All
Direct Hernias	<age 65

Problematic co-morbid conditions

Chronic obstructive pulmonary disease
Benign prostatic hyperplasia
Chronic constipation
Ascites from hepatic cirrhosis

Essentially all femoral hernias merit repair. Indirect hernias probably should be repaired at any age in otherwise fit individuals. Of course, it is often difficult to be certain whether the hernia is an indirect or direct type. As a general statement, essentially all hernias in adults under age 65 should be considered for repair. Persons over this age with asymptomatic direct hernias may not deserve repair. Traditional open hernia repair may not be wise in persons with chronic obstructive airway disease because of the high recurrence rate in these individuals with increased expiratory effort. Likewise, patients who have stranguria from benign prostatic hyperplasia probably should not have hernia repair until the urinary obstruction has been corrected. Occasionally, patients with chronic constipation may have habitual excessive straining which may make recurrence rates abnormally high.

When one judges whether to recommend operation for a given patient one has to consider the patient's age, fitness, and co-morbid conditions vs. the patient's discomfort from the hernia plus the

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potential risk of strangulation. Statistically, the risk of strangulation may be .3% per year per hernia or 4% the remaining life time of an older individual.[2] Consequently, in an elderly individual who is not well the risk of strangulation may not be sufficient to warrant repair with the inherent risks of anesthesia, deep vein thrombosis, infection (even though small) and the like. Even when strangulation occurs, the patient can usually have a satisfactory repair if surgical attention is sought promptly. Clearly then an operative risk of 0.5% cannot be justified in many asymptomatic patients.

The Risk of Recurrence

Miller and colleagues of the Mayo Clinic compared the success of unilateral vs. bilateral repair in 659 patients (330 unilateral and 329 bilateral repairs) followed for over nine years. The type repair was not taken into consideration. They found no difference in the frequency of recurrence in bilateral repairs as opposed to unilateral repairs. Recurrence rates for unilateral repairs were 4.8% at 5 years and 8.8% at 9 years. Failures in bilateral cases were 5.0% at 5 years and 9.1% per side at 9 years (i.e. 1% per year per operation)![3]

Panos and associates in a large teaching hospital compared the McVay repair to the Shouldice repair in a prospective randomized study of 308 open repairs in 269 patients in a large teaching hospital.[4] Repairs for bilateral henias were staged 6 weeks apart. Recurrence rates were 8.8% for the McVay and 6.6% for the Shouldice repair! Results in either of these series are meritorious.

Other recent reports have been more laudable. The Shouldice Clinic has done about 200,000 inguinal hernia repairs with ±1% recurrence.[5] Obese patients are not accepted for operation. Mesh was not used in inguinal repairs, but is now routinely used in femoral repairs since recurrence before using mesh was 6% in femoral hernias.[6] The writer has been using the Shouldice repair for 20 years and has had one known recurrence, but has made no systematic follow-up. The Lichenstein group has reported on 3,000 repairs with similar results, but routinely uses a piece of polypropylene mesh.[7] Early return to work is encouraged by these surgeons. The popularity of the Lichenstein operation continues to increase over the U.S.

What is the recurrence rate with laparoscopic repairs? Early laparoscopic repairs with stuffing of mesh in the inguinal canal had high rates of recurrences. A recently completed multicenter trial experienced recurrences in 4.7%, but one surgeon using an extraperitoneal approach has no recurrences in 87 cases.[8] Using current laparoscopic techniques many surgeons, including the writer, feel their recurrence rate is under 1%.[9,10] Acceptable methods are transabdominal preperitonal or completely extraperitoneal repair using sizable pieces of mesh or more than one piece of mesh. However, no long-term follow-up studies are available. Of the recurrences that have been noted after endoscopic repair, most have been in the early postoperative period. The theoretic disadvantage of the endoscopic repairs remains the same as that of the Lichenstein repair – the use of foreign material (mesh) with a potential for an increased risk of infection. Thus far this has failed to materialize.

The recurrence rate is probably highly dependent on the individual surgeon's skill as well as the specific technique. The surgeon who has a recurrence rate of 2% or less with the prompt return of his patients to work has little justification for change. On the other hand, if the recurrence rate is more than 2%, then some other method of hernia repair including an endoscopic method needs to be considered

Anesthesia

Open repairs can be done with local anesthesia, block type anesthesia (spinal or epidural) or general. There is no documentation that one form of anesthesia for hernia operations is more safe than the others. Many surgeons prefer local since the patient can be asked to strain during the procedure to test the adequacy of the repair and can be up immediately. Others favor a block anesthetic since the patient will have absolute relaxation, can be awakened during the procedure to cough just as with local, and will experience no pain with the operation. Still other operators prefer general since this affords absolute relaxation, the patients can usually be awakened immediately, and therefore, have less likelihood of urinary retention that might happen with a spinal. For endoscopic repairs almost all surgeons use general anesthesia.

Selection of Type Repair

When considering an endoscopic type repair the surgeon may do a completely extraperitoneal approach or a transperitoneal preperitoneal approach. The former avoids any direct contact with the intestine and affords the surgeon finite anatomical landmarks by providing immediate visualization of the pubis and Cooper's ligament. The transperitoneal approach allows ready inspection of the contralateral side where an occult hernia may be found 15 to 20% of the time, a wide field of view and direct assessment of any viscera which may be within the

sac. The writer selects the kind of repair depending on the type of hernia.(Table 2). Obviously, the patient should be apprised of the options and allowed to participate in the decision as to what procedure he or she prefers. For a unilateral indirect hernia in a young person an open repair is recommended. Our personal preference for open repairs is the Shouldice technique with continuous 3-0 Prolene suture, but no mesh. For bilateral hernias, recurrent hernias, or femoral hernias, an endoscopic repair is recommended. I employ the preperitoneal approach exclusively for endoscopic repair unless there is some contraindication such as a prior suprapubic prostatectomy or femoro-femoral bypass graft. The transperitoneal approach would be used for persons with some contraindication to the extraperitoneal approach or for a large sliding hiatal hernia. Not all hernias fall into one of the categories in the Table; and the surgeon should use his own biases to select the specific procedure with special situations.

Table 2

TYPE REPAIR RECOMMENDED

Open

Unilateral indirect inguinal herniain a young person

Strangulated hernia

Endoscopic

Extraperitoneal

Femoral hernia

Biateral inguinal hernias

Recurrent hernia

Transperitoneal

Contraindication to an extraperitoneal approach

Large sliding hernia

Return to Work

The Lichenstein group which routinely uses mesh and Rutkow, who uses a plug mesh and overlying patch, uniformly recommend immediate return to work as soon as the subsiding discomfort allows.[11] The writer has recommended early return to work after the Shouldice repair for the last 12 years. Though patient compliance has not been ideal, there appears to be no difficulty from this. Brooks compared the open plug mesh technique to the transabdominal, preperitoneal, laparoscopic approach and found sooner return to work after the laparoscopic repair.[12] Essentially all laparoscopic surgeons recommend immediate return to work after laparoscopic repair. Consequently, the patient should expect to return to work within 2 weeks or sooner or should have clarification why this is not feasible by the surgeon.

Summary

Groin hernias are one of the major problems handled by the surgeon. At this time there appears to be some clear indications for open repair, pretty clear indications for laparoscopic repair, less clear indications for one type anesthesia or the other. There has been a major shift toward utilizing mesh in open repairs and in laparoscopic repairs with no significant increase in complications. Patients should usually be able to return to work, even at labor, within two weeks of the operation. Surgeons and patients should expect to experience a recurrence less than 2% of the time.

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Exercise and the Breast Cancer Patient

*by Kennon Francis, PhD**

Cancer is a leading cause of premature death in the United States, second only to cardiovascular disease.[1] Of the 250 million Americans now living, about 75 million will eventually have cancer.[2] Over eight million Americans alive today have a history of cancer, five million diagnosed five or more years ago.[1] People with persisting, recurrent, or metastatic cancer require additional treatment, but at least 15% of this latter group has been estimated will still be alive 15 years after the diagnosis has been first made.[3] Increased survival for cancer patients has brought quality-of-life issues, self-care activities and social activities into prominence.[4] The issue of "how well a patient lives" has become as important an issue as "the number of years lived."[5]

Cancer and its treatment are often characterized by a variety of symptoms including pain, decreased appetite, nausea, vomiting, a general deterioration of physical fitness and fatigue.[4] Of all the symptoms, generalized weakness and lack of functional capacity are without doubt the symptoms most commonly experienced.[4,6] It can be the first manifestation of the underlying disease process and it can be enhanced by subsequent treatments such as radiation, chemotherapy or immunotherapy.[4,7,8] The final stages of the cancer process are often characterized by exhaustion and a complete loss of energy.[4,7,9] It has been estimated that one-third or more of the decline in functional capacity experienced by cancer patients can be attributed to hypokinetic conditions that develop as a consequence of prolonged physical inactivity.[3,10] A combination of generalized weakness, loss of functional capacity and muscle atrophy combined with depression of mood state is characteristic of many patients with advanced disease.[5,9,11,12] Thus, the consequences of physical inactivity significantly impinges on the detrimental effects of a patients quality-of-life.

Despite the fact that patients who are chronically ill with cancer can experience symptoms that may modify their ability to exercise, evidence from other types of chronic diseases as well as promising information collected from cancer patients, in particular breast cancer patients, suggest that cancer patients might benefit from an exercise program.[13-17]

In one of the first reported studies to determine the effect of exercise on breast cancer patients, MacVica and Winningham[18] evaluated the effect of a progressive, interval training exercise program on the physical and psychologic responses in six cancer patients undergoing adjuvant chemotherapy for breast cancer. Patients, exercising three times per week for 10 weeks at an intensity of 60 - 85% of maximum were compared with four non-exercising patient control and six exercising, healthy age-matched controls as shown in Figure 1. They found that exercising patients and exercising healthy subjects made comparable gains in functional capacity. Breast cancer patients who exercised (PE) demonstrated a pre-to-post-test increase in oxygen uptake of 20.7% (from 1.37 to 1.73 liters of oxygen), as compared with an increase of 17.4% (1.67 to 2.02 liters of oxygen) for the healthy, age-matched controls who exercised (HE). The non-exercising patients (PC) decreased 1.8% during the experimental period declining from 1.11 to 1.09 liters of oxygen.

Psychological changes determined by using Total Mood Disturbance (TMD) of the Profiles in Mood State questionnaire in these patients showed a more dramatic reduction in overall mood disturbance from pre-to-post-test in both exercise groups.[18] Cancer patients reduced their TMD scores dramatically from 50.6 to 7.7 and healthy, age-matched controls showed similar reductions from 45 to 3.6. In contrast, non-exercising controls showed an increase rather than a decrease in TMD scores from 19.4 to 38.6 (Figure 1).

In another study on the effect of aerobic exercise training on controlling common symptoms contributing to disability/rehabilitation in 48 cancer patients, Winningham and MacVica[19] demonstrated a significant decrease in reports of nausea after 10 weeks of exercise. Sixteen breast-cancer patients receiving adjuvant chemotherapy and who exercised at 60-85% of maximum for 10 weeks, three times per week were matched with 16 similar types of patients who only performed stretching and flexibility types of exercises (placebo group) during the exercise periods. These groups were compared to 12 control patients who received no treatment and simply con-

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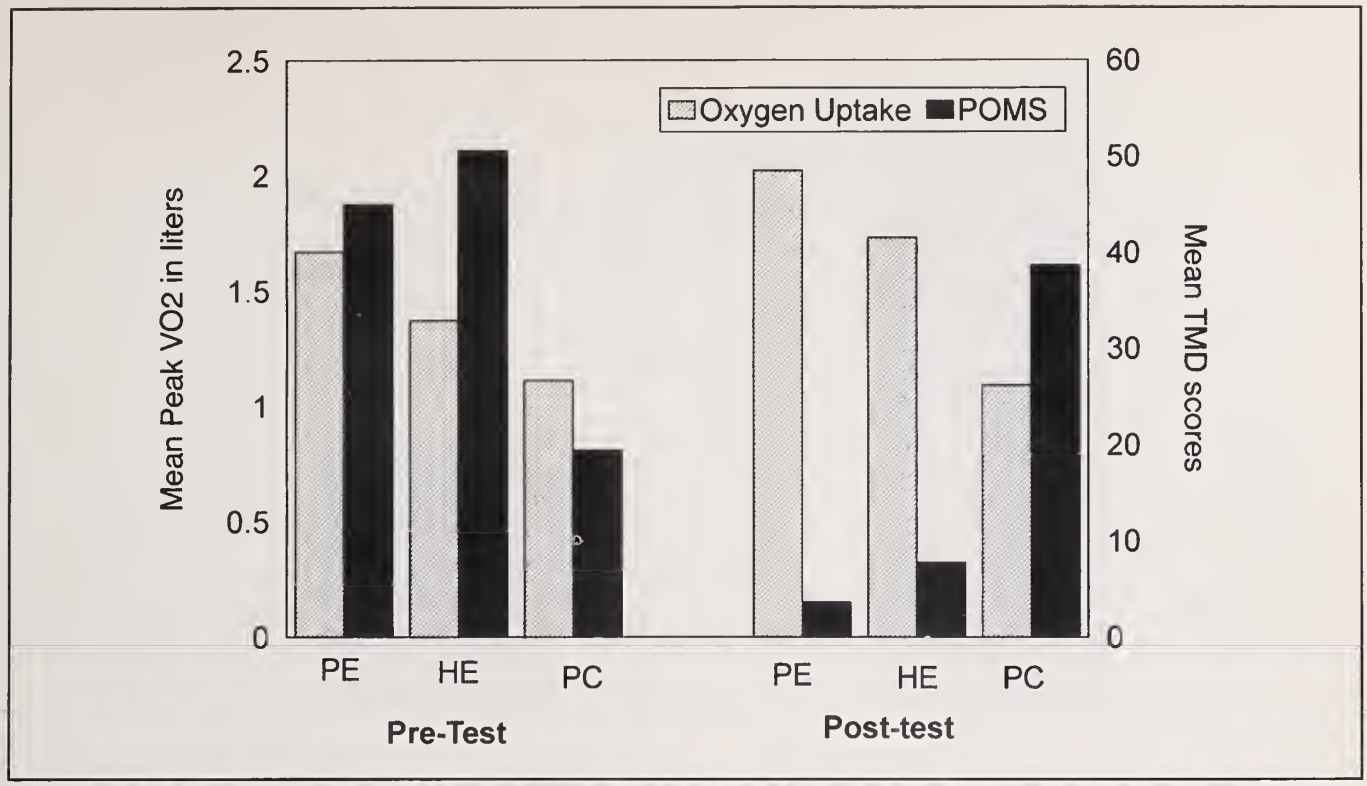


Figure 1 *– Pretest-to-post-test mean oxygen uptake and mean total mood disturbance scores in three groups – exercising patients (PE), non-exercising patient controls (PC), and healthy, age-matched controls (HE). The total mood disturbance score is obtained by adding the responses to the six subscales of the Profile in Moods State Questionnaire. The range of scores may be from -32 (low mood disturbance) to 200 (high mood disturbance). Adapted from MacVicar and Winningham, The Cancer Bulletin, 38:235-238, 1986.*

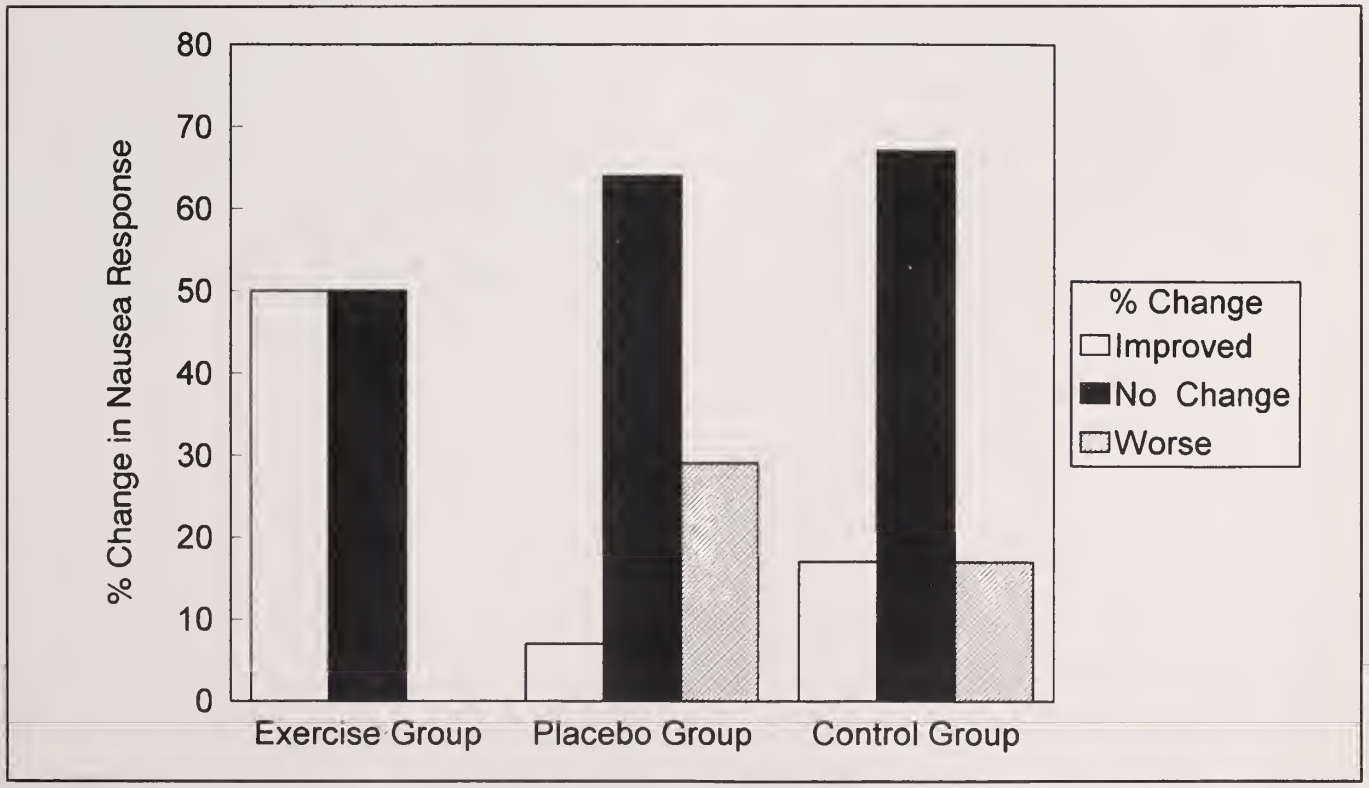


Figure 2 *– Percent changes in nausea responses of three groups of cancer patients – exercise group (n=16), placebo group (n=14), and a control group (n=12). Nausea is defined as subjective self-report using a five point distress scale consisting of item descriptors ranging from "not-at-all" to "extremely". Adapted from Wnningham and MacVicar, Oncology Nursing Forum, 15:447-450, 1988.*

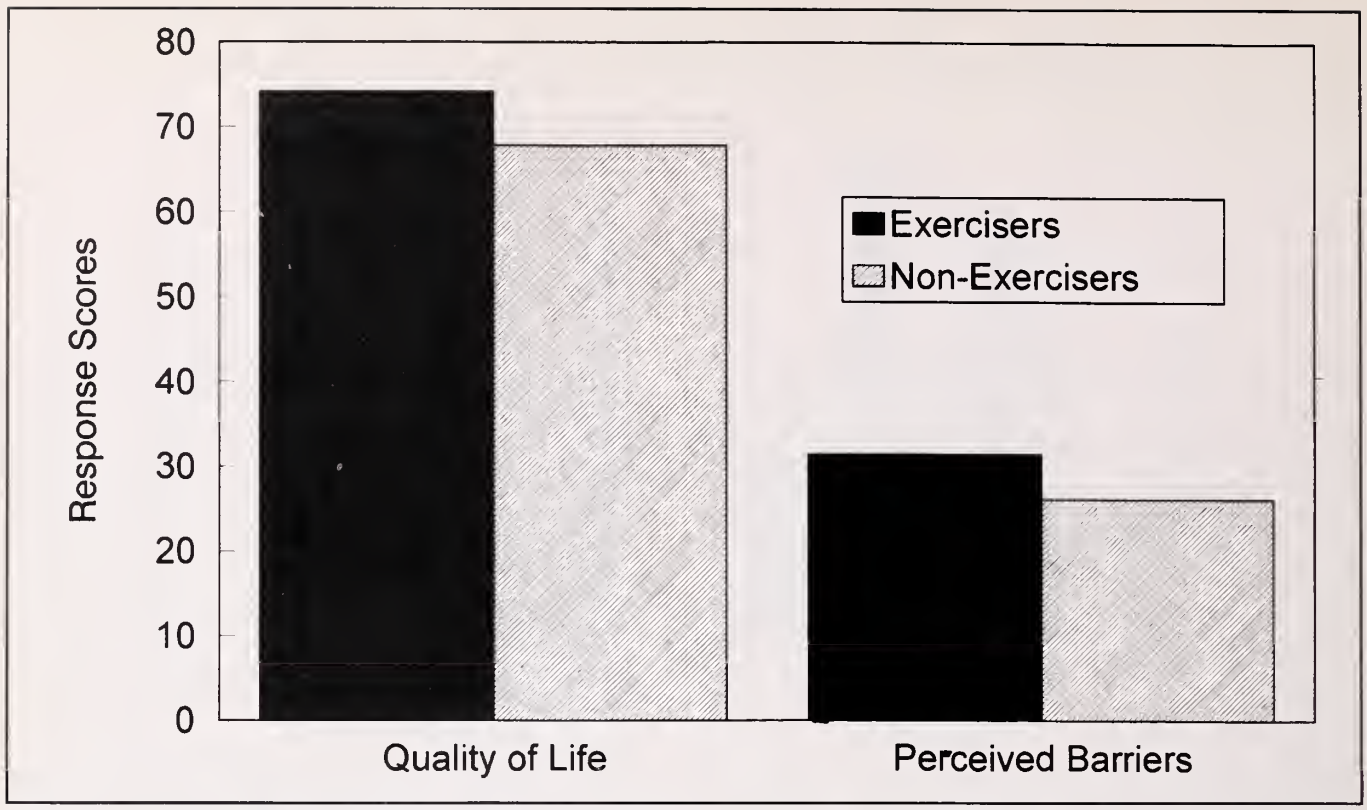


Figure 3 *– Comparison of mean Total Quality of Life Score and mean Total Barriers to Exercise for cancer patients who exercise (n=42) and cancer patients (n= 29) who do not exercise. Mean scores for Total Quality of Life Score can range from 0-100. Higher scores indicate a higher quality of life. Scores on Perceived Barriers can range from 8-40. A lower score indicates more perceived barriers to exercise. Adapted from YoungMcCaughan and Sexton, Oncology Nursing Forum 18:751-757, 1991.*

tinued their normal activities during the 10 week period. Feeling of nausea was measure before and after the 10 week training period. The exercise group showed a marked improvement in nausea compared to the placebo group and the control group. Fifty percent of the exercise group reported an improvement in nausea verses only a 7% improvement in the placebo and 17% in the control group (Figure 2). Whereas none of the patients in the exercise group indicated a worsening of nausea during the 10 week period, 29% of the placebo and 17% of the control group indicated they became more nauseous during this time period.

More recently, MacVica and Winningham[20] studied the effect of a 10 week aerobic interval-training exercise program on functional capacity (VO_2max) of 45 women receiving chemotherapy for treatment of Stage II breast cancer. Subjects were stratified by baseline functional capacity and randomized to experimental (n=18), placebo (n=11), and control (n=16) groups. Exercise patients completed a 10 week, 3 times/week exercise training program at an intensity ranging from 60-85% of maximum. The placebo group participated in 10 weeks of non-aerobic stretching and flexibility exercises while the CO group maintained normal activities performed before the initiation of the study. A 40% improvement of $V0_2$max was achieved by the exercise group from pre- to post test improving from a pre-test value of 1.02 liters of oxygen consumption to a post-test of 1.45 liters of oxygen consumption. VO_2 max of the placebo and control groups did not significantly change significantly during the 10 week period. These data show that the intervention protocol was effective in promoting adaptation of the aerobic physiological energy systems of the exercise patients.

The effect of aerobic exercise on quality of life has also been assessed in a retrospective study by Young-McCaughan and Sexton.[21] Using a questionnaire of quality of life that included major life areas of functional ability, social interaction, comfort, health, and economics, a group of 42 women who had been treated for breast cancer who regularly exercised was compared to a group of 29 women who did not exercise. Compared to non-exercisers, the women who exercised reported a higher quality of life score on everyone of the 19 items of the questionnaire. The overall total quality of life score for the exercisers was 74.1 ± 12.6 vs 67.8 ± 11.6 for the non-exercisers (Figure 3). Likewise exercisers reported fewer perceived barriers to exercise than non-exer-

cisers. Out of a total score that could range from 8-40 with the lower score indicating more perceived barriers, exercisers reported a total score of 31.4 ± 5.1 whereas non-exercisers reported a score of 26.2 ± 3.8.

The results of these studies, even though they are few in number with relatively small sample sizes, suggest that regular exercise might play a significant role in physical and psychological rehabilitation from the effects of breast cancer. This evidence appears to be promising for arguing for the cancer patient to maximize physical activity. There seems to be good reason to encourage physical activity in those who have breast cancer whether or not the conditions appears "curable" as a means of retaining functional capacity, independence, and quality of life for as long as possible. For patients whose cancer is in regression, exercise provides another rehabilitative tool to assist in restoring them to optimal functioning after treatment.

Although these studies did not identify many cancer related reasons for not exercising, there are contraindications and indications for caution to exercise for patients with breast cancer under certain circumstances. A partial list of contraindicators includes: unusual fatigability, vomiting within the previous 24-36 hours, severe diarrhea within the previous 34-36 hours, pallor, sudden onset of dyspnea, and intravenous chemotherapy within the previous 24 hours.[22] Physicians need to discuss with patients how to exercise safely as well as how the patient may re-establish a normal relationship with their previous surroundings.

Due to the limitations of a lack of empirical data, there remain many unanswered questions regarding excise and the breast cancer patient which await further study. For example, aerobic exercise appears to be a recommended component of the rehabilitative process, yet it is unknown how often should the patient exercise at what intensity for what duration to optimize the beneficial effects.

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Computerized Patient Records

*by Robert H. Story, M.D.**

OUTPATIENT RECORDS

The Situation

Health care professionals are becoming more and more frustrated with their ability to deliver care using as their support tool the paper medical record. Health care is the last of the information industries almost entirely dependent on paper, although information is constantly increasing. This problem must be remedied by new tools such as computerized patient records. The computerized patient record (CPR) or the electronic medical record (EMR) programs are much more convenient and useful than they were even a short while ago. Despite their usefulness, less than one percent of the physicians in the United States are using CPRs was reported in the September 1994 issue of Family Practice [Solomon, 1994]. In The February 6, 1995 issue the American Medical News reported, "experts figure only about five percent of physicians currently use electronic patient records" [Borzo, 1995]. In the six months between the time these two articles were written, many programs for the CPR-EMR were sold. The CPR-EMR is an emerging technology which is hitting this nation like a tidal wave. George O. Thomasson, M.D., director of risk management for COPIC Insurance Company, states confidently, "Most doctors will computerize their patient records within five years" [Borzo, 1995]. The medical community has recognized a technology whose time has arrived! In Britain, eighty to ninety percent of the generalists (family doctors) have computerized records in their offices [Cross, 1994]. There are many reasons cited for the difference between office medical records in Britain and the United States including the fear of computers by American doctors; however, I suspect the more important reasons have to do with reimbursement and fear of suits by the American doctor. The tide is changing as doctors learn that electronic records will reduce the chance of a law suit by eliminating transcribing errors, by giving more legible records, and by allowing the doctor to practice better medicine through practice guidelines.

The Problems

3675 County Road 45, Tuskegee, AL, 36083. Dr. Story is a member of the Board of Censors.

Privacy

According to a recent poll, fifty one percent of Americans see computerized medical records as a threat to their privacy [Anderson, 1995]. Americans have more confidence in the handling of confidential information by doctors and nurses than by others, including medical researchers, hospital staff, and insurance companies. Privacy is very important to Americans, much more than it is to the British; however, the public does not realize that their privacy has already been compromised by the selling of mailing list by companies and governments. Anyone who has a computer and only a little money can learn almost anything he wants to know about another person.

The most privacy of computerized medical records would be gained by everyone's having a secret number and no names being attached to the record. Only the patient would know his number (like the PIN number with the ATM card), and no one could gain access to a person's record without that number. It would be necessary that everyone have a bracelet, card, or tattoo with his number so that if the person reaches a medical facility unconscious, his records can be accessed. Twenty-one percent of Americans oppose having such a number. Because no system is or can be absolutely secure, an alternative way to make the information relatively secure is to require every inquiry to be logged in; no one could gain access without identifying himself; then if information is leaked, all persons who have accessed the information can be quickly identified. Another possibility would be to put a person's medical information on a smart card. The technology exists to put thirty two kilobytes of information (about sixteen typewritten pages) on a card the size of the average credit card. This would be more than enough space for the medical information on most people. According to an article in the *Journal of the American Medical Association*, these cards could be produced for about fifteen cents each [Sklonich, 1994].

Habits

Doctors have historically done charting as a narrative; this prose is less useful than a database would be, but habits are hard to change. Many doctors cannot type and others do not want to type; therefore, a program must require minimal typing

skills in order to be generally accepted. Creation of a database without typing is difficult, but by using templates, the typing can be reduced to a minimum. Most doctors indicate they prefer voice recognition computers so they can just talk to it and the machine will do their will; however, the technology is not quite that good yet. Voice recognition programs are not as good as the average transcriptions in determining what the doctor said. Voice recognition is also the most expensive technology used in CPR programs. An electronic record dictated will be in the word processor format rather than the database format unless some templates are used. Keyboard entry is the least expensive form of data entry and is probably the best even for the nontypist.

Fits

One size does not fit all; CPRs designed for emergency room physicians frequently cannot be adapted to a family practice setting, or a CPR program designed for an internist will not be adaptable for use by an orthopedist. Most CPR programs are written for one specialty and successful modification for use by a different specialty is sometimes difficult if not impossible.

The Incentives

American physicians have recently gained several new reasons for going to computerized patient records. At least two insurance companies have lowered their rates for professional liability to doctors who use software that prompts them to ask the correct questions and order the proper tests. A five percent discount will be given by Medical Professional Liability Agency to doctors who use the programs ClinacLogic, PharmcoLogic, and HealthLogic. Michigan Physicians Mutual Liability Company is giving a two percent discount to physicians using any CPR that meets seven criteria: the ability to document

1. the history and physical,
2. progress notes,
3. allergies,
4. medications,
5. procedures,
6. test results, and
7. patient no-shows

Several other carriers have indicated they are looking at similar discounts. In some cases the savings generated by the discounts could pay for the system in two to five years. [Borzo, 1995].

Health Maintenance Organizations are asking for data that can be most easily supplied by a computerized patient record. As more and more people are insured by HMOs, the need for this data becomes increasingly important [Anderson 1995]. Many HMOs are demanding outcome data as well as disease prevention by cost effective screening. Some require reports on the number of Pap smears and mammograms ordered as compared to the number recommended by their "clinical guidelines". Immunization rates of children is important and is one of the "quality parameters" frequently checked by HMOs – this information is almost impossible to obtain unless the records are on computer.

The Potential

Clinical Guidelines.

Most physicians will agree that there is a best way to treat a patient, but every physician has his own way of treating each disease or injury. The treatment is often one he learned while in training, and he may not have learned anything new on this subject in the past five years. Usually, a physician feels his approach is the best; if he knew a better way, he would be using it. Clinical guidelines are an attempt to select the best way to treat a particular disease or syndrome. "In the past five years, research organizations, clinical specialty organizations, payers, private companies, and even the federal government have developed more than four thousand clinical guidelines. These efforts to limit variations in medical practice are a part of the search for what researchers term The Holy Grail—the least expensive and most effective way to treat a diagnosis "[Bazzoli, 1995]. There are many problems with the guidelines; one criticism is that they demand "cookbook medicine"; many believe that payers (insurance companies) will only adopt guidelines that save money, while clinical specialty organizations will only adopt guidelines that help their members; on the other hand, the federal government spent several years and in excess of a million dollars developing clinical guidelines for just one diagnosis. Despite these rather significant concerns, the real problem with the clinical guidelines is that they are long and complex, and few practicing physicians will have the time to actually learn all of the guidelines that impact the diagnoses that he treats. Automation may put the guidelines at the fingertips of the physician while he is actually seeing the patient. If the guidelines were incorporated into the record system, the computer could suggest the recommendations to the physician as he orders test and treatments. The physician could reject the recommendation from the guidelines, but it is generally accepted that most physicians would follow the guidelines if they were available as he was doing the orders.

Cost Containment

The most common reason for a test being repeated is that the results of the first test are not available. Insurers, especially HMOs, are convinced that

money can be saved if a physician has all the necessary information. A recent study suggests that fifteen to thirty percent of medical cost could be saved if doctors had adequate information when making decisions [Bennahum, 1995]

Dr. Jonathan Edelson, chairman and CEO of Med-E-Systems has convinced insurance companies that the system will save them enough money so that the insurance companies in the Dearborn, Michigan area have furnished the entire system including wireless PDAs to twelve doctors in the Dearborn area at no cost to the physician. This eliminates the conflict between a sedentary mainframe computer and a highly mobile physician [Bennahaum, 1995]. These PDAs can not only recommend to the doctor the most cost efficient treatment, but after the doctor has selected the treatment, the PDA can print the prescription or call it into the drugstore. Med-E-Systems has created a series of translators that can interface between different databases. Each healthcare provider that joins Med-E-Systems has a translator designed to interface with each database he uses (hospital, lab, drugstore, etc.) Most of the early attempts at computerized patient records seemed to miss the point that patient care is the primary mission of healthcare providers [Dunbar, 1991]. Doctors care for patients – anything that will help him care for patients better he will use if it does not cost him too much time or money. The biggest hurdle in getting doctors to use CPRs is their inertia [Bennahum, 1995]. Most doctors are hardworking, dedicated, caring, conservative, people who hate change. But if he can be shown it will save him money and provide better care for his patients, the physician will embrace the change. Most physicians have no clue that using paper records is costing him five hundred to a thousand dollars per month in labor cost that would not accrue if he used CPRs. One physician reported his partner and he pay an average of seven hundred and fifty dollars per month in transcription fees to have their office notes typed. Another physician reported labor costs for pulling and replacing patient records was five hundred and forty dollars per month [Solomon, 1994]. If, as estimated by one knowledgeable physician, it costs about fifty thousand dollars to go to CPR, and if this system will last five years, then it could be financed for five years with monthly payments very close to the paper cost saved each month [Solomon, 1994].

The Needs

"Physicians today are faced with 'data overload' and, paradoxically, 'information underload' – the inability to locate pertinent, needed knowledge in a sea of data with which they are inundated" [Greenes, 1989]. This data overload caused Dr. Gary Fox to start using his laptop computer on rounds just to prevent his overlooking some important bit of information. Using "off the shelf" software, he was able to use the laptop very profitably. Initially, he used it for drug interaction programs, dementia scales, and risk assessments. Simple "to-do lists" were his next move; he wanted a computer generated reminder; but he was soon using the computer in patient management. Fox tried both word processor software and database software; he found that the word processor was easier to use, but the database, while more difficult to learn, was more useful in the long run [Fox, 1994]

The National Academy of Science's Institute of Medicine (IOM) did a comprehensive study of clinical computing in 1991. This study which was published in the book The Computer-based Patient Record: An Essential Technology for Health Care gave twelve attributes that a CPR should have [Dick and Gabler, 1995]. The twelve key CPR attributes are:

1. "Problem List"
2. "Measures of Health Status and Functional Levels",
3. "Documents Clinical Reasoning and Rationale",
4. "Longitudinal CPR and Timely Linkages with Other Records on Patients",
5. "Confidentiality, Privacy, and Audit Trails",
6. "Continuous Access for Authorized Users",
7. "Supports Simultaneous Multiple User Views Into the CPR",
8. "Supports Timely Access to Local and Remote Information Sources",
9. "Facilitates Clinical Problem Solving",
10. "Supports Direct Data Entry by Physicians",
11. "Supports Practitioners in Measuring and Managing Costs and in Improving Quality",
12. "System has Flexibility to Support Existing and Evolving Needs of Each Specialty"

According to Dick and Gabler, while great improvements have been made, none of the programs for CPRs available today have all twelve of these attributes. These authors "believe that the CPR holds the potential to do for healthcare what the transistor has done for electronics. That is, the CPR will enable a host of capabilities the likes of which we can hardly imagine today"[Dick and Gabler]. If these experts were less well known or less respected, these remarks might be considered self-serving; Richard S. Dick, Ph.D. is chairman and chief executive officer of ASCEN-Technologies, Inc. This company is committed to establishing databases concerning CPR systems for consumers. James M. Gabler is with The Analytical Sciences Corporation, which is setting up a certification lab for CPR software in conjunction with ASCEN-Tech-

nologies.

INPATIENT RECORDS

The Situation

Many of the medical centers in this country are actively trying to go to computerized records, IBM has a contract to put all of the University of Alabama at Birmingham hospitals and clinics on-line with CPRs. The contract calls for the pilot program to be working before December 31, 1995, and for all units to be on-line before December 31, 1996. Many university and training hospitals are working on this same project. The transition is easier for university and training hospitals because the "doctors in training" are more malleable than the doctors who have practiced for a while. One hospital administrator said her doctors are comfortable holding a traditional paper chart, but they are distinctly uncomfortable with a computer.

In their attempt to move to electronic records, hospitals have other problems besides their medical staff. Joint Commission (the accrediting entity for most hospitals) only recognized computerized patient records in the past year, and it is not clear if they will accept electronic signatures. Medicare has not indicated it is ready to accept electronic signatures. The state of Alabama requires that a hospital keep its records for twenty-three years; the health department has indicated that storage of charts electronically is acceptable, but the courts have not yet made a ruling on the subject so most hospitals are afraid not to keep some of the documents on paper. Many hospitals have every part of their chart in electronic form before it is converted to paper except the doctor's progress notes and the nursing notes. There would be many advantages for the hospital record being completely electronic; the hospital would save money, but more importantly the easy retrieval of data would allow better patient care.

In most hospitals that use the traditional paper record, the current information is on scratch paper in someone's pocket; the nurse's aid has the latest vital signs in her pocket; the nurse has her latest assessment of the patient in her pocket, and the IV nurse has the time she hung the current fluids in her pocket. All or almost all of this important information will eventually get on the chart. With the electronic chart, this information is never written it is entered immediately into the database allowing all appropriate members of the healthcare team immediate access.

The Need

Data integration and reorganizational tasks are necessary in order to provide more time available to health care providers for "patient care" rather then "paper care". Clerical duties of professional providers must be eliminated so that they can continue to give good patient care. CPRs can contribute to the changes for healthcare providers. A system provides a complete on-line lifetime medical record, from which current and past medical history and events can be immediately accessed.

The Potential

In February 1995, Bill Gates, Microsoft's founder and chairman, in a speech to the Healthcare Information and Management Systems Society stated "I can't think of another industry that is changing as fast or that has as much opportunity to improve efficiency and quality of service" [Morrissey, 1995]

Because of integration around a single database, all information can be accessed from any workstation, based on enterprise-defined security and access parameters. Some systems have a "chart" review function which has been designed to give providers immediate and personalized access to desired information. This eliminates errors of omission. Data is divided into significant and less significant categories. Also, new technology provides display for comparative graphics and available pictures such as X-rays or surgical sections.

Case management, practice parameters, protocol-based quality management, and utilization-controlling techniques all affect health care. The CPR will allow administrative considerations in real time, alerting providers or reviewers to actual or potential problems. In addition to the overall promotion of cost effective quality care, many features of the system are attractive to physicians because it makes them better informed by providing functions such as preadmission, chart review, result reporting, order completion, messages, concurrent discharge processing, and order entry. When a nurse at the hospital calls the doctor in his office about a patient in the hospital whose condition has deteriorated, the doctor can call-up that patient's chart on his PDA and can review all the appropriate data, and then enter his orders directly in the chart, thereby eliminating the need for a verbal order (verbal orders have a high percentage of errors).

Also, with the record on computer an unlimited source of data is maintained for research and analysis.

The Equipment

The best hardware on which to build a computerized medical record has not been established. Some vendors are using mainframes with clinical workstations (dumb terrninals), others are using

the client-server architecture with personal computers as the workstations [Bunschoten, 1995]. Some systems use a combination of dumb terminals and personal computers as workstations depending on the complexity of the task to be performed at that workstation. Sometimes the decision about the architecture of the system is based on compatibility with the hardware owned by the facility. Microsoft's leap into the healthcare field may complicate the movement toward a common language. Up to now the popular "standard" has been UNIX.

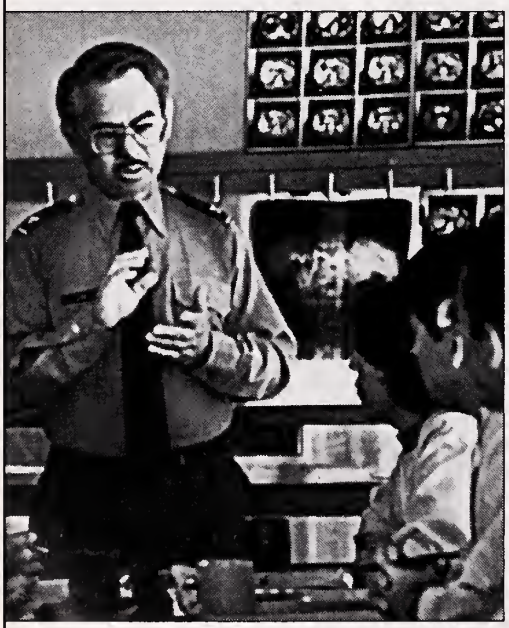
Mobile computers have captured the imaginations of some in the healthcare field. While some feel the technology is mature enough to warrant utilization, others disagree. Only three years ago there were no wireless systems designed for medical use, but now it seems that the majority feel wireless is better than being wired for mobile professionals like the doctor and the nurse. The technical capabilities of the hardware continue to improve while the size and cost continue to decrease. One system has the medication cart with a built in personal computer and radio transmitter so that when the nurse enters a dose of medication in her medication administration record it is immediately a part of the CPR. Wireless technology is usually spread spectrum or cellular digital packet data. Earlier fears about interference have been proven unfounded as the portable devices used in hospitals utilize such a low power that no interference occurs. User interface can be a keyboard; a touch screen; a pen device; or voice recognition. All of these devices have their disadvantages, a miniature key board can be difficult to use, errors are frequent with a touch screen, the pen devices that use handwriting recognition are fraught with inaccuracies, and voice recognition technology is not yet dependable [Deming, 1995].

The Reform

The United States Department of Defense is presently doing "Healthcare Reform". The cornerstone of their reform efforts, according to Lieutenant Colonel Beverly Blessing is the "Composite Health Care System". CHCS is a database computerized medical record. The new system is designed to:

1. Increase patient access to military health care.
2. Reduce patient delays in receiving diagnostic results, treatments, and prescriptions.

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3. Provide patients more responsive scheduling of appointments

Col. Blessing admits they do not have the programs all worked out. She reports that the inpatient physician's order is a major difficulty. The outpatient order screen has to be designed for a specific doctor will almost always utilize the same tests and the same treatments over and over.

It is very important that a CPR not be an electronic copy of the paper record; we must have databases that prompt us to do the correct procedure and then provide data showing we did the correct procedure or data that explains why we did not do the correct procedure.

For eighteen months, the Alabama Healthcare Reform Task Force worked diligently to find feasible ways to improve health care for this state. There was only the briefest mention of the computerized patient record in the information presented to the taskforce, because a year ago the CPR was still in its infancy. The Task Force has sent five recommendations to Governor James through the State Committee of Public Health. Although as Chairman of the Task Force I spent many hours studying, listening, and discussing healthcare reform, I feel that computerized patient records will do more to reduce the cost and improve the quality of medical care than any or all of the five recommendations sent to the governor!

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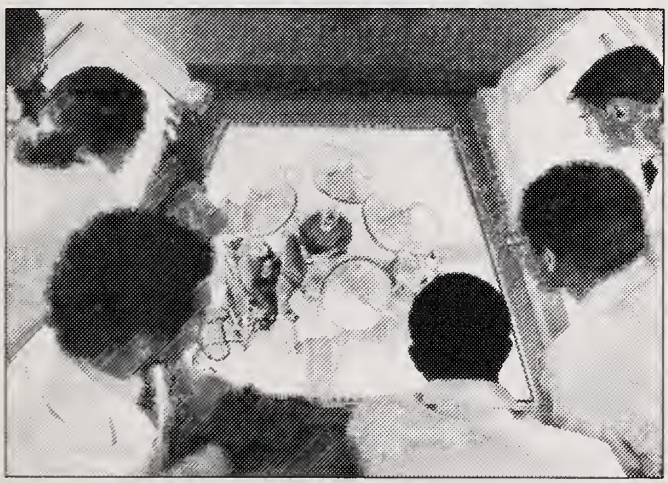
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The New Medical Ethics and Religion

*by Ernest S. Campbell, M.D., FACS**

Most commonly, when there is an impasse between medicine and religion, it is apt to be in the period when life is ebbing away – usually in an adult who is dying and for whom continued aggressive treatment, in the best medical judgment, would be futile. The same can be true, however, for the seriously ill infant whose condition is incompatible with life but the parental religious conviction is that everything possible should be done and that God will take care of the rest. Courts have been divergent in their opinions regarding withdrawing life support but generally have affirmed the right of competent patients to refuse life-saving medical therapy, causing society and most physicians to give up on maintaining biological life at all costs. How physicians respond when the faith-based preferences of an autonomous patient (or the patient's surrogate) clash with the medically indicated treatment modality has been changed by subtle but major changes in medical ethics.

Changes in the way we deal with medical problems have been brought about by factors in five major areas.

1. Landmark court cases dealing with moral conflict.
2. Highly publicized problems in clinical research.
3. New technologies posing hard moral questions.
4. A social revolution in matters of individual rights dealing with race, gender, sex and institutional accountability.
5. Intrusion by government through Congressional committees and commissions with mandates to bring new ethics to medical research and practice.

LANDMARK COURT CASES

Karen Quinlan 1976 – This young woman's parents sought to have a ventilator disconnected after five months of coma due to overdosing on drugs and alcohol – an action opposed by the hospital and physicians. After removal of the breathing device, she lived another nine years – sparking other court cases involving removal of feeding tubes.

Nancy Cruzan 1990 – Nancy Cruzan was in a coma for eight years after an auto accident. Her parents requested removal of a feeding tube. Missouri law does not allow removal of life support without specific patient instructions. The Supreme Court declined to change the Missouri refusal to give relief to the Cruzan family. With evidence of the patient's desires in writing or verbally, it became morally acceptable and legal to turn off the machines and even food and fluid when all hope of recovery of cognitive function was gone.

The evolution has been from the religious "God's will be done" to doing everything possible to prolong life to advanced directives, living wills and health care proxies. The primary good of medicine went from defense of life to serving the will of the patient, especially in terminal illness, coma or abortion. The tendency also seems to be for the courts to follow the public mood; e.g. Massachusetts courts will not force blood transfusions on non-consenting adult patients of the Jehovah's Witness faith. The legal standpoint is important, to be sure, and the legal dimensions of an issue must be considered in an ethical analysis. However, law is not ethics but is society's sanctuary of secular religion – complete with robed high priests and other ministers of the court along with statutes and case law as its bible. Because something is legal, however, doesn't make it right – just arguable.

MISADVENTURES IN RESEARCH

In 1963 the Sloan-Kettering Cancer Institute administered cancer cells at the Jewish Memorial Hospital to unsuspecting elderly patients. Black males in the Tuskegee study (1932-1972) were involved in an evaluation of the natural effects of untreated syphilis without their consent or understanding. Retarded children were given live hepatitis virus to study the onset of this deadly disease in the Willowbrook case. The Department of Energy directed studies of government sponsored radiation experiments in the 1960's.

All these studies were done with the flawed ethical judgment that the end (of advancing clinical medicine) justified almost any means. Deception was used – all of these studies were completed after the Nuremberg trials for medical war crimes, and the centerpiece of the Nuremberg code was full and free informed consent.

These deceptions resulted in new Federal regulations, caused the advent of local review boards (IRBs), and established informed consent as a bedrock in research and patient care. Were the religions which

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formed the foundation of the medical ethics guiding these researchers out of step with the times?

NEW TECHNOLOGIES

Developed for the use of polio patients, the artificial respirator soon found use with comatose diabetics and drug overdoses – some with irreversible brain damage. Some feel that this started the modern era in medical ethics; that is, whether or not and when to remove a patient from the ventilator.

The A-V shunt for ambulatory renal dialysis caused possibly the first ethical dilemma; how to choose this service for the few patients out of the overwhelming numbers who needed it. Choices were made by a very unpalatable "God Committee," soon disbanded but stimulating Congress to enact federal supported universal entitlement to dialysis.

Christian Barnard, M.D., reported in 1968 the first human heart transplant. The ensuing debate prompted Congressional hearings on the criteria for death and the heart still usable; and the methods for selection of donors and recipients. These hearings caused the eventual formation of the National and Presidential Commissions.

More recently, assisted reproduction (in vitro fertilization), genetic engineering with recombinant DNA and all its ramifications and the genome project have brought new moral dilemmas.

SOCIAL CHANGES

Many liberal social changes have occurred since 1960, most without major input from organized religion. Most religions have gotten on the bandwagon of social revolution either late or not at all. The violent opposition to the Viet Nam war was associated with attendant changes in sexual mores and an assertion of gender and racial equality. There has also been a general assertion of individual human rights along with the development of a patient's Bill of Rights in 1973. Promulgated by the American Hospital Association, it stressed full disclosure to the patient, truthtelling, and the patient's right to self-determination.

Finally, the rubella epidemic of the early 1960s and the thalidomide concern created an open demand for more abortions, with the public moral debate being polarized by *Roe vs. Wade* in 1973. This seemed to crystallize religious thinking, giving them a "*raison d'etre*," and the "religious right" taking a stand "for life" against abortion. These same groups have now interpolated this stand into opposition to genetic engineering with recombinant DNA.

GOVERNMENT COMMISSIONS

The National Committee for Protection of Human Subjects of Biomedical and Behavioral Research was the outcome of the Congressional hearings of 1973. A Presidential Commission from 1979-1983 insured broad public exposure to the problems of ethics and bioethics; and made recommendations to the Secretary of HEW that became guidelines for federally funded clinical research; the Belmont Report establishing ethical principles required for medical research and practice; standardization of the definition of brain death; foregoing life-sustaining therapies; making health care decisions and securing access to health care.

Historically, religion and medicine are interrelated; both dealing with the same human mysteries – birth, suffering, dying and death. Each reflects the other to a certain extent. Hippocrates, the father of Medicine, was religiously oriented; writing, "Before the Gods, the physicians bow since they have not superabundance of power in their art." At the same time, he was the first to separate medicine from philosophy and the role of the physician from that of a priest. That said, however, once religion is introduced into the discussion of patient care, it becomes a part of the overall plan of patient care and must be addressed. Problems raised by new technologies and new social mores cannot be answered by the Hippocratic tradition of medical ethics but insightful physicians can respond to perceived religious convictions by non-argumentative methods, providing consolation, assuaging guilt and offering hope, but not attempting to change deeply set beliefs. Saving and maintaining life is no longer supreme when that life is tied to a machine or when that life represents biological existence without human meaning. Medical paternalism ("the Doctor knows best") is out of step with the newly enunciated rights of individual self-determination and justice. Evolution of the new medical ethics is occurring and is being taught in medical schools, changing as it had to, with the times.

To physicians who are agnostic or even atheistic these ideas may not seem so incomprehensible. For many doctors who are professedly religious, the need for accommodation of their faith to modern thought might be insurmountable; and for believers who follow the dictates of their heart, faith has its own reason; to quote Pascal, "we know truth not only by reason but also by the heart . . . the heart has reasons which reason does not know." But there need not be antagonism between faith and reason, between religious views and medical judgments. Medical providers, religious or not, can suggest to the patient that a "mysterious Providence" is at work in a way that is in harmony with the usual order of things.



Usha Bhuta
A-MASA President

Let's Roll Up Our Sleeves

I Held a moment in my hand
Brilliant as a star
Fragile as a flower.
A tiny sliver of one hour.
I dropped it carelessly.
Oh God! I knew not
I held opportunity.

("What might have been")
by Hazel Lee

Have you lost an opportunity because you didn't act in time? That stock you were ready to buy and suddenly the phone rang and you were interrupted; "do you have a second to talk?" and then the interruption was interrupted by the call waiting and then you had to run somewhere because you were getting late. After a year you found that the stock you didn't buy tripled in value and if you bought at that time you would have been rich today (it happens to my husband all the time!).

Do you know that some people's time is more important than others. When my children were preten (I mean under 10 years of age), I used to take them to parks and zoo at their demand. One day my daughter came to me jumping with joy and announced: "Mommy, Mommy, we are going to the zoo tomorrow with Daddy. Do you know what? He is even going to turn his beeper off!" It sure didn't make me feel great at that time but then I realized that in my time management children are my top priority and in my husband's time management surgery and patients are his top priority. When he makes rounds patients don't jump with joy because it's a routine. We have to manage our time according to the demands we have in our lives.

It is a fact that time was here before we were. Time goes with same speed but for some of us it flies and for some of us it stands still to let us watch "Days of our lives." The President of the United States has the same time as the person who does nothing but crossword puzzles. Time is life, and how we use it defines our life. Time cannot be bought by money, cannot be invented by a scientist and cannot be saved for tomorrow. Time is money, particularly when it is over time!

I use time as an excuse. When I fail to do some thing or don't feel like doing something my response is "I just didn't have time" or "I didn't find the right time to start the job" or "If I only knew of my duties in time." Who am I fooling, myself or others? Did I say yes to some one and accept a position as chairman or a board member? I do feel great when I get all that mail which I never read, at least my mailman is impressed. Sometime I know exactly what I have to do but don't get started.

Summertime is vacation time so I think I will wait (I am so sure every body will lock their doors for three months and go to Europe or to the lake or beach if you live in Alabama). It will be so rude to bother people when they are getting their children situated in schools; I will wait. Then I almost start (and get the result just like a woman who was almost pregnant). Then comes Thanksgiving, then Christmas, then New Year, then my flu and then my aunt. I realize that I was grounded before take-off. While sitting and watching the installation of new officers I tell myself I wish I could do it over but it's too late because the time cannot be recovered when lost.

We have to get busy right now to achieve our goals we have set for this year! We have a very capable group of individuals who want to make a difference in Medical Alliance. LET US ROLL UP OUR SLEEVES BEFORE TIME FLIES AWAY!


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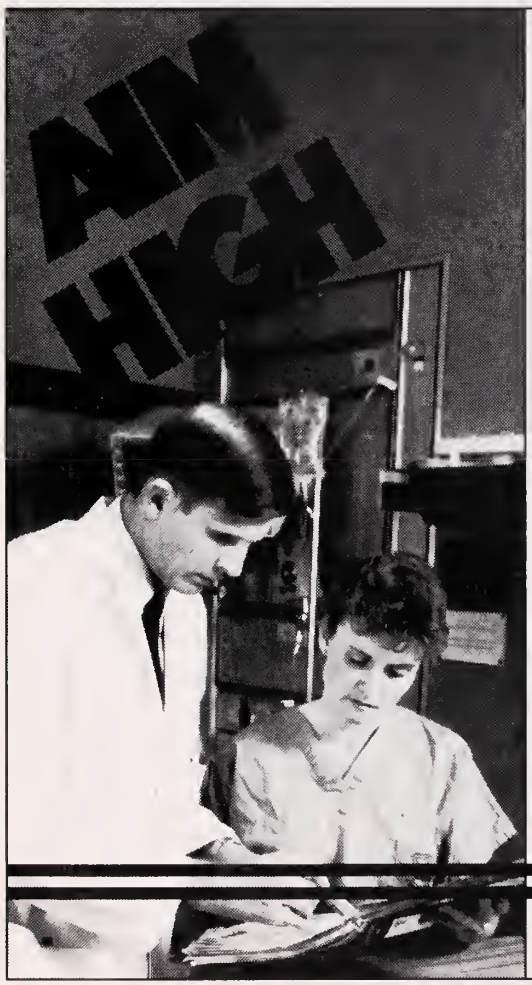
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